Third Edition

Clinical Laboratory Management

Lynne S. Garcia, Editor-in-Chief

Edited by **Timothy C. Allen • Vickie S. Baselski**
Deirdre L. Church • Donald S. Karcher • Michael R. Lewis
Andrea J. Linscott • Melinda D. Poulter • Gary W. Procop
Alice S. Weissfeld • Donna M. Wolk

Clinical Laboratory Management

THIRD EDITION

Clinical Laboratory Management

THIRD EDITION

Lynne S. Garcia, EDITOR IN CHIEF
LSG & Associates, Santa Monica, California

EDITORS:

Timothy C. Allen
Corewell Health, Royal Oak, Michigan

Vickie S. Baselski
University of Tennessee Health Science Center, Memphis, Tennessee

Deirdre L. Church
University of Calgary, Calgary, Alberta, Canada

Donald S. Karcher
George Washington University, Washington, DC

Michael R. Lewis
Banner MD Anderson Cancer Center, Gilbert, Arizona

Andrea J. Linscott
Ochsner Medical Center, New Orleans, Louisiana

Melinda D. Poulter
University of Virginia, Charlottesville, Virginia

Gary W. Procop
American Board of Pathology, Tampa, Florida

Alice S. Weissfeld
Microbiology Specialists, Inc., Houston, Texas

Donna M. Wolk
Geisinger, Diagnostic Medicine Institute, Department of Laboratory Medicine, Danville, Pennsylvania

ASM PRESS
Washington, DC

WILEY

Copyright © 2024 American Society for Microbiology. All rights reserved.

Copublication by the American Society for Microbiology and John Wiley & Sons, Inc.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means electronic, mechanical, photocopying, recording, scanning, or otherwise, except as permitted by law. Advice on how to reuse material from this title is available at http://wiley.com/go/permissions.

The right of Lynne S. Garcia, Timothy C. Allen, Vickie S. Baselski, Deirdre L. Church, Donald S. Karcher, Michael R. Lewis, Andrea J. Linscott, Melinda D. Poulter, Gary W. Procop, Alice S. Weissfeld, and Donna M. Wolk to be identified as the editor(s) of this work/the editorial material in this work has been asserted in accordance with law.

Limit of Liability/Disclaimer of Warranty
While the publisher and author have used their best efforts in preparing this book, they make no representations or warranties with respect to the accuracy of completeness of the contents of this book and specifically disclaim any implied warranties or merchantability of fitness for a particular purpose. No warranty may be created or extended by sales representatives or written sales materials. The publisher is not providing legal, medical, or other professional services. Any reference herein to any specific commercial products, procedures, or services by trade name, trademark, manufacturer, or otherwise does not constitute or imply endorsement, recommendation, or favored status by the American Society for Microbiology (ASM). The views and opinions of the author(s) expressed in this publication do not necessarily state or reflect those of ASM, and they shall not be used to advertise or endorse any product.

Editorial Correspondence:
ASM Press, 1752 N Street, NW, Washington, DC 20036-2904, USA

Registered Offices:
John Wiley & Sons, Inc., 111 River Street, Hoboken, NJ 07030, USA

For details of our global editorial offices, customer services, and more information about Wiley products, visit us at www.wiley.com.

Wiley also publishes its books in a variety of electronic formats and by print-on-demand.
Some content that appears in standard print versions of this book may not be available in other formats.

Library of Congress Cataloging-in-Publication Data

Names: Garcia, Lynne Shore, editor.
Title: Clinical laboratory management / Lynne S. Garcia, editor in chief ; editors, Timothy C. Allen, Vickie S. Baselski, Deirdre L. Church, Donald S. Karcher, Michael R. Lewis, Andrea J. Linscott, Melinda D. Poulter, Gary W. Procop, Alice S. Weissfeld, Donna M. Wolk.
Other titles: Clinical laboratory management (Garcia)
Description: Third edition. | Hoboken, NJ : Wiley ; Washington, DC : ASM Press, [2024] | Includes bibliographical references and index.
Identifiers: LCCN 2023053671 (print) | LCCN 2023053672 (ebook) | ISBN 9781683673910 (cloth) | ISBN 9781683673927 (adobe pdf) | ISBN 9781683673934 (epub)
Subjects: MESH: Laboratories, Clinical–organization & administration | Clinical Laboratory Techniques | Clinical Laboratory Services–organization & administration
Classification: LCC R860 (print) | LCC R860 (ebook) | NLM QY 23 | DDC 610.72/4–dc23/eng/20240108
LC record available at https://lccn.loc.gov/2023053671
LC ebook record available at https://lccn.loc.gov/2023053672

Cover Design: Wiley
Cover Image: © Marco VDM/Getty Images
Interior Design: Susan Brown Schmidler

Set in 10.5/12pt Minion Pro by Straive, Pondicherry, India

Contents

Contributors *xxii*
Preface *xxv*
Acknowledgments *xxvi*

SECTION I
Basic Concepts and the Current Healthcare Environment 1

1 Clinical Laboratory Management: Basic Principles and Practices 3
Paul Wesolowski and Susan D. Roseff

Management, Leadership, and Administration 3
A Brief History of Management Concepts 4
Classical Theory • Behavioral Theory • Quantitative Theory • Operations Management and the Integrated Theory
Decision Making and Problem Solving 9
What Is Decision Making? • Types of Decisions • Individual versus Group Decision Making • The Problem-Solving/Decision-Making Process
Management Functions 12
Planning • Organizing • Directing • Controlling • Summary
The Evolving Models of Clinical Laboratories 16
Centralized Testing • Decentralized Testing
The Basics of Financial Management 17
Costs • Revenue • Gross versus Net Revenue • Medicare • Managed Care • Budgeting • Operating Budget • Capital Budget • Revenue Cycle: Billing and Collecting
A Brief History of Clinical Laboratory Finances 19
Management Ethics 19
SUMMARY 20
KEY POINTS 20
GLOSSARY 21
ACKNOWLEDGMENTS 22
REFERENCES 22
APPENDIXES 23

2 Regulatory Issues in Laboratory Medicine 25
Glenn Ramsey and Christina E. Anderson

Introduction 25
Brief History of Regulation of the Clinical Laboratory 25
Department of Health and Human Services and CLIA • FDA and Medical Devices
Overview of the Current Clinical Laboratory Regulatory Environment 27
CLIA and the Regulation of Quality 27
CLIA Framework • Quality Control
Accreditation and Licensure 29
Laboratory Inspection and Accreditation • Personnel Certification and Licensure
FDA Regulation of *In Vitro* Diagnostic Tests 33
Current Overview • Laboratory-Developed Tests
Regulations Affecting Transfusion Medicine 34
Introduction • Framework of FDA Regulations • Blood Collection and Component Production • Transfusion Services • Reporting Requirements • Cellular Therapies • Current and Future Regulatory Challenges
Clinical Laboratory Workplace Safety 36
Risk Assessments • Chemical Hazards • Biological Hazards • Other Infectious Hazards • Transportation of Clinical Specimens • Physical Hazards • Additional Safety Regulatory Resources

Overview of Laboratory Reimbursement Regulation 42
U.S. Healthcare • Medicare • Pathology and Laboratory Services in Medicare • Claims Processing • Reimbursement for Physician Services • Laboratory Test Reimbursement
Patient Privacy: HIPAA and Related Regulations 44
HIPAA Introduction • Protected Health Information • Patient Informed Rights • Consent and Authorization • Privacy Rule • Security Rule • HITECH and Omnibus Rule • Breach Notification Rule • Enforcement Rule • Current Topics in HIPAA Compliance • Summary of Laboratory Responsibilities
SUMMARY 47
KEY POINTS 47
GLOSSARY 47
ACKNOWLEDGMENTS 48
REFERENCES 48

3 The Changing Practice of Medicine 53
Elizabeth A. Godbey, Susan D. Roseff, and Denise E. Russell

Introduction 53
Staffing Shortages 53
Pathology Pipeline
Consolidation of Hospital Systems, Hospitals, and Physician Practices 54
Health Disparities 55
The Impact of Technology 56
Electronic Health Records • Patient Access to Information: Recent Changes to the HIPAA Rules • Molecular Testing
Stewardship of Limited Resources 58
Supply Chain Instability • Laboratory Utilization • Blood Products
Medicolegal Issues 60
Malpractice Pre-COVID-19 • Malpractice in the Age of COVID-19 • Public Readiness and Emergency Preparedness Act
Climate of Medical Training 61
Trainee and Physician Well-Being
SUMMARY 61
KEY POINTS 61
GLOSSARY 62
ACKNOWLEDGMENTS 63
REFERENCES 63

4 The Changing Healthcare Environment 67
Steven M. Armstrong and Sandra L. Lamm

Introduction 67
Changing Provider Payment Models 68
Overview of Reimbursement Methods • Types of Managed Care Organizations • Managed Care and the Clinical Laboratory
Impact of Healthcare Reform 71
Patient Protection and Affordable Care Act
Payment Reform and Provider Reimbursement Strategies 74
Medicare Shared Savings Program • Value-Based Purchasing (VBP) • Other Payment Reforms • Hospitals and Laboratories: Concerns in Healthcare Reform
The Changing Legal Environment 77
HIPAA • False Claims Act
Technological Advances 77
Changing Testing Modalities • Pathology Informatics • Meaningful and Relevant Information • Impact of Bioinformatics on Pathology
Direct Consumer Access 80
Direct Access Testing • Direct-to-Consumer Testing
Consolidation in the Healthcare Industry 82
Consolidation of Practices • Integrated Delivery Systems • Internal Consolidation in Hospital Laboratories • Regional Integrated Laboratory Networks
Strategies for Future Success 84
Strategic Redesign • Supply Chain • Laboratory Design • Developing System-Wide Thinking and a Common Culture • Training Adequate, High-Quality Laboratory Professionals for the Future Workforce • Pathologist Shortage • Moving from Top-Down Management to Bottom-Up Customer Focus • Evidence-Based Medicine
SUMMARY 86
KEY POINTS 87
GLOSSARY 87
REFERENCES 89

SECTION II
Managerial Leadership 93

5 The Foundations of Leadership 95
David S. Hefner and Katharine R. Becker

Introduction 95
Distinguishing Management from Leadership 95
What Is "Leadership" and How Do You Become a Leader? • Management • Leadership

The First Foundational Factor Is Integrity 97
The Definition of Integrity • Honoring Your Word • The Pitfalls in Honoring Your Word • What Is Your Word? • What Is the Current State of Your Word? • Trust and Its Relationship to Honoring Your Word • Preparation for Making a Commitment or Giving Your Word
The Second Foundational Factor Is Authenticity 100
The Definition of Authentic • Knowing Yourself • How Do You Respond in Various Situations? • The Importance of Context • The Path to Authenticity
The Third Foundational Factor Is Commitment to Something Bigger than Yourself 102
Succeeding as a Leader • What Happens Next?
SUMMARY 103
KEY POINTS 104
ACKNOWLEDGMENTS 105
REFERENCES 106
APPENDIXES 107

6 Employee Needs 108
Kathleen G. Beavis

Introduction 108
Definitions and Background 108
Special Challenges from the Pandemic 109
Strategies for Assessing and Reducing Burnout 109
Additional Trends and Needs of Laboratory Employees 111
The Role of Generational Differences 114
SUMMARY 114
KEY POINTS 114
GLOSSARY 114
ACKNOWLEDGMENTS 114
REFERENCES 114

7 Motivating through Intelligent Leadership 116
Christa Pardue

What Is Motivation? 116
Leadership as a Conduit of Motivation 117
Knowledge of Self 117
Creating the Vision • Humility • Work-Life Balance and Basic Needs
Knowing What Others See in You 118
Factors of Motivation • The Right People Need the Right Leader • Actually Fix the Problems
Knowing the Emotions of Leading 119
Emotional Intelligence • The Need for Purpose • Human Motivation Theory
SUMMARY 121
KEY POINTS 122
GLOSSARY 122
REFERENCES 122

8 Effective Communication 123
Marianna Hofmeister

Introduction 123
Channels of Communication 124
Formal Channels of Communication • Informal Channels of Communication
Types of Communication 124
Oral Communication • Telephone Communication • Written Communication • Online Presentations • Electronic Communication • Visual Communication • Body Language and Other Nonverbal Communication
Barriers to Effective Communication 128
Physical Barriers • Nonverbal Barriers • Verbal Barriers • Psychological Barriers
The Importance of Listening 128
Effective Listening • Ineffective Listening • Stages of Listening • Types of Listening
Elements of Effective Face-to-Face Communication 130
Skills for Effective Face-to-Face Communication • Organizational Climate • Using Body Language • Using Positive Language
Leadership Essentials for Improving Communication 131
The Interaction Process • Adapting Communication Styles
SUMMARY 132
KEY POINTS 133
GLOSSARY 133
ACKNOWLEDGMENT 133
REFERENCES 133

9 Effective Meetings 135
Mark G. Hanly

Introduction 135
Things To Do before a Meeting 136
Determine If There Is a Need for a Meeting • Determine What Type of Meeting Is Needed • Develop the Agenda • Use of the Consent Agenda • Determine Whom To Invite to the Meeting • Determine the Venue of the Meeting • Determine the Technology/Equipment Required for the Success of the Meeting

Things To Do during a Meeting 139
Things To Do after a Meeting 140
Calculating the Cost of a Meeting 141
Recurrent Meetings 141
How To Be an Effective Participant in a Meeting 141
SUMMARY 141
KEY POINTS 142
GLOSSARY 143
REFERENCES 143

10 Conflict Management 144
Christopher Naugler

Conflict Is Natural and Inevitable 144
Origins of Conflict 145
Conflict Resolution Styles 146
Conflict Management 147
Equity, Diversity, and Inclusion Considerations 148
When Conflict Resolution Fails 148
What the Organization Can Do 148
SUMMARY 149
KEY POINTS 149
REFERENCES 149

11 Leading People Through Change in Pathology and Laboratory Medicine 151
Gabriel E. Ayala

Introduction 151
The Case for Change Management 152
Definition of Change • The Psychology of Change • Why Change Management Is Important • Sources of Change • The Need for Change
Models of Change Management 153
The Kotter Model • The ADKAR Model
Supporting Laboratory Staff Through Change 155
Actions Leading to Successful Change • Managing Resistance • Auditing and Reinforcing the Change
SUMMARY 157
KEY POINTS 157
GLOSSARY 157
REFERENCES 157
APPENDIX 158

SECTION III
Personnel Management 159

12 Employee Selection 161
Anthony S. Kurec

Introduction 161
Diversity, Equity, and Inclusion (DEI) in the Workplace 162
Criteria-Based Job Descriptions (CBJD) 164
Basic CBJD Requirements • Criteria-Based Job Description Review • Minimal Personnel Requirements
Search Process 167
Search Committee • Advertising
Interview Process 169
Screening Résumés • Interview Formats • Interview Questions • Interview "Do's and Don'ts"
Hiring Process 172
Candidate Selection • Orientation and Onboarding • Documentation
Separation from Service 174
Retention • Losing an Employee • Progressive Discipline • Termination
SUMMARY 178
KEY POINTS 178
GLOSSARY 179
REFERENCES 179

13 Performance Appraisals and Competency Assessment 182
Lynne S. Garcia

Introduction 182
Performance Appraisals 182
Definition and History of Performance Appraisals • Purpose of Performance Appraisals • Advantages of Performance Appraisals • Trends Beyond the Traditional Performance Appraisal • Appraisal Types: Formal and Informal Appraisals • Responsibility for Developing a Performance Appraisal Program • Legal Aspects of a Performance Appraisal Program • Elements of a Meaningful Formal Performance Appraisal • Competency-Based Appraisals • Rating Methods • Other Types of Performance Appraisals • Who Should Perform the Appraisal? • Preappraisal Preparation • Steps to a Successful Performance Appraisal Interview • Benefits of Becoming a Mentor • Salary Adjustments • Strategies To Reinforce Appropriate

Behaviors • Guidelines for Appraising Poor Performers • Dealing with Emotional Outbursts during Performance Appraisals • Completed Performance Appraisal Documents • Improvement Plan • Web-Based Software Products and Websites

Competency Assessment 194

Regulatory Foundation for Competency Assessment • Timing of Competency Assessment • Methods for Assessment of Competency • Practices • Personnel Excellence

SUMMARY 197

KEY POINTS 197

GLOSSARY 198

REFERENCES 199

APPENDIX 201

14 Staffing and Scheduling 202

Patti Medvescek

Introduction 202

Laboratory Personnel: Current Dynamics Affecting Staffing 202

Labor Shortage • Business Need • Increasing Opportunities for Medical Technologists

Personnel Requirements 203

Education • Training and Competence Assessment • Functional Definitions • Generalist versus Specialist

Laboratory Staffing 205

Staffing Requirements • Basis for Determination: Workload Recording

Staff Scheduling 207

Key Success Factors • Metrics for Success • Alternatives • Special Considerations • Flexible Staffing

SUMMARY 210

KEY POINTS 210

GLOSSARY 210

REFERENCES 210

APPENDIX 211

15 Teams, Team Process, and Team Building 212

James W. Bishop, Dow Scott, Stephanie Maynard-Patrick, and Ji-Yeon Seok

Introduction 212

Definition of a Team 213

Types and Classifications of Teams • Why Define "Team" So Precisely?

Guidelines for Choosing Whether To Have Teams 214

Common Purpose • Interdependent Tasks • Costs: a Cautionary Note

Group Process and Teams 216

Selecting Team Members 217

Task- and Process-Related Training

Leading Teams 219

General Ideas about Leadership: a Brief Review • Leadership in a Team Environment • Team Leader Selection

Goal Setting, Performance, and Rewards 220

Goal Setting and Performance • Goal Setting and Teams • Evaluating Teams and Team Members • Rewarding Team Members

Virtual Teams and Remote Work 222

Global Teams (a Special Case of Virtual Teams) 223

SUMMARY 223

KEY POINTS 224

GLOSSARY 224

REFERENCES 224

APPENDIX 225

16 Labor Relations 226

Emily A. Snavely and Lynne S. Garcia

Introduction 226

Labor Law 226

National Labor Relations Act (Wagner Act), 1935 • Fair Labor Standards Act (Black Act), 1938 • Labor-Management Relations Act (Taft-Hartley Act) • Labor-Management Reporting and Disclosure Act (Landrum-Griffin Act) • 1974 Amendments to the NLRA • Labor Law Updates

National Labor Relations Board (NLRB) 230

Description • Function • Structure • Processing of Cases • Authority To Secure Injunctive Relief from a Court • Issues Related to the NLRB

Union Structure 231

Formal Structure • Union Membership • Function of the Union Steward

Unionization Process 232

Individual, Group, and Union Image: Reasons Why Employees Join a Union • Relevance for Healthcare Workers

Organizing Campaign 233

Authorization Cards • The Bargaining Unit • Information Distribution and Solicitation • Election • Certification

Collective Bargaining 235

Issues for Bargaining • Preparation Phase • Negotiation Phase • Administration of the Agreement • Management Rights Clause • Labor Actions and Disputes

SUMMARY 237

KEY POINTS 237

GLOSSARY 237

REFERENCES 239

APPENDIXES 240

17 Workplace Drug Testing and the Clinical Laboratory 242

Lindsay A. L. Bazydlo

Introduction 242

Regulated and Nonregulated Testing 243

Whom To Test 243

Preemployment Testing • For-Cause or Reasonable Suspicion • Random Testing • Posttreatment Testing

Urine Drug Testing Protocol 244

Specimen Collection • Specimen Testing • Specimen Validity • Urine Drug Screening • Urine Drug Confirmation • Reporting Results

Alternative Specimen Types 248

Managing Clinical and Forensic Drug Testing 248

SUMMARY 249

KEY POINTS 249

GLOSSARY 249

ACKNOWLEDGMENTS 249

REFERENCES 250

APPENDIX 250

SECTION IV

Requirements for Effective Laboratory Management 251

18 Quality Management 253

Lynne S. Garcia

Introduction 253

Quality Management of Preanalytical Processes 254

Test Selection and Ordering • Quality of Specimen Collection • Patient and Client Satisfaction • Specimen Transport, Storage, and Receipt and Preanalytical Processing

Quality Management of Analytical Processes 257

Method Selection and Evaluation • Quality Control • Quality Control Rules • Frequency of Quality Control Analysis • Specification of MAE • Use of Patient Data for Quality Control • External Quality Control (Proficiency Testing)

Quality Management of Postanalytical Processes 263

Turnaround Time 263

Corrected and Incomplete Reports 264

Document Control 264

SUMMARY 264

KEY POINTS 265

GLOSSARY 265

ACKNOWLEDGMENTS 266

REFERENCES 266

APPENDIXES 269

19 International Organization for Standardization 271

Anne Marsden and Amy Shahtout

Introduction 271

ISO Background 271

ISO Certification versus ISO Accreditation • "Shall"/"Should"/"May"/"Can" Explained

ISO 9001 272

Seven Principles of ISO 9001 • Standards Related to ISO 9001

ISO 15189 274

Structure of ISO 15189 • Important Principles of ISO 15189 • Documents Related to ISO 15189 • ISO 15189 versus ISO 9001 • CLIA '88 and ISO 15189 • International Requirements for ISO 15189 Accreditation • Considerations for the Laboratory Management Team • Approaching ISO 15189 Accreditation • Accreditation Bodies for ISO 15189 • CAP as an Accreditation Body

SUMMARY 277

KEY POINTS 277

REFERENCES 277

20 Effective Communication in Laboratory Management 278

Andrea Linscott and Elise Occhipinti

Introduction 278

Delivering the Message 279

Communicating to Diverse Audiences 280

Means and Mechanics of Effective Communication 280

Spoken Word • Written Word • Intradepartmental Communication • Interdepartmental Communication • External Communication

SUMMARY 283

KEY POINTS 283

GLOSSARY 283

ACKNOWLEDGMENT 283

REFERENCES 283

21 Laboratory Information Systems 285

Melinda L. Doherty and Kenneth E. Youens

Introduction 285

A Primer on Computers 286

Hardware • Software • Networking • Cloud Computing

Healthcare Information Systems 287

Laboratory Information System Fundamentals 288

LIS Architecture • LIS Interfaces • LIS Administration • LIS Selection and Implementation

Specialty Considerations 293

Microbiology • Blood Banking • Point-of-Care Testing • Molecular Diagnostics

SUMMARY 294

KEY POINTS 294

GLOSSARY 295

ACKNOWLEDGMENTS 297

REFERENCES 297

22 Management of Point-of-Care Testing 298

Laura Smy, Kristine Apfeld, Sarah Ampomah, and Molly Thieme

Introduction 298

Organizational Management of POCT 299

Administrative Considerations • Setting Goals for POCT Management • Laboratory Certification and Accreditation • Developing Management Structures for POCT

Operational Management of POCT 301

Determining the Scope of POCT Services • Weighing POCT versus Alternatives • Analyzing Costs of POCT • Assessing the Benefits of POCT Services • Quality Management of a POCT Program

Technological Management of POCT 309

POCT Innovation • Pandemics, Mass Casualties, and Humanitarian Emergencies Driving POCT Innovation • New Monitoring Technologies

SUMMARY 310

KEY POINTS 311

GLOSSARY 311

ACKNOWLEDGMENTS 311

REFERENCES 311

23 Principles of Preanalytic and Postanalytic Test Management 315

Lynne S. Garcia and Andrea J. Linscott

Introduction 315

Preanalytic Activities 316

Test Selection and Implementation • Appropriate Test Utilization • Specimen Acquisition, Transport, and Storage • Test Ordering

Postanalytic Activities 325

The Report • Storage and Retention • Assessment of Test Results on Patient Outcomes

SUMMARY 329

KEY POINTS 329

GLOSSARY 329

ACKNOWLEDGMENTS 330

REFERENCES 330

24 Selection and Implementation of New Equipment and Procedures 333

Paula Revell and Lakshmi Chandramohan

Introduction 333

Defining the Laboratory's Requirements 334

Technical/Performance Considerations 335

Specimen Type • Specimen Volume • Test Menu • Testing Volumes • Turnaround Time/Batch Size • Operational Throughput • Automation and Digitalization • Open versus Closed Platform • Available Interface • Assay Performance • Regulatory Clearance/Approval • Reagent Availability • Control Availability

Physical and Technology Requirements 337

Space Requirement • Power • Data • Plumbing/Water • Temperature/Humidity • Supply Chain Logistics

Human Resources 337

Staffing • Workflow • Ease of Use • Training Requirements

Financial 338

Instrument Cost • Cost of Operation • Cost per Result • Warranty • Maintenance Contract • Consumable Costs • Disposable and Consumable Cost • Software Requirements • Evaluation and Validation • Personnel Costs

Prioritization of Requirements 338

Confidentiality and Conflict of Interest 339

Information Review 339

Implementation and Product Placement 340

Verification and Validation 340

Verification • Validation

Personnel Competency Assessment and Training 341

Proficiency Testing 341

SUMMARY 341

KEY POINTS 342

REFERENCES 342

25 Laboratory Safety 343

Cameron A. Brown and James J. Dunn

Introduction 343

Safety Management Plan and Responsibilities 344

Laboratory Hazards 344

Biological Hazards • Chemical Hazards • Physical Hazards • Radiation Hazards • Mental Hazards

Standard Precautions 346

Hazard Prevention and Containment 347

Risk Assessment • Handwashing • Barrier Protection • Engineering Controls • Work Practices • Respiratory Protection • Immunization • Warning Signs and Labels • Biological Safety Cabinets and Chemical Fume Hoods

Sterilization and Decontamination 354

Spill Management 355

Biological • Chemical

Fire Safety 356

Disaster Preparedness 356

Waste Management 356

Regulatory Oversight • Management Program

Packaging and Shipping Infectious Substances 357

Infectious Substances Classification • Packaging, Labeling, and Shipping Regulated Material

Personnel Training 359

Training Program • Methods • Documentation • Monitoring and Evaluation

SUMMARY 361

KEY POINTS 361

GLOSSARY 361

REFERENCES 362

APPENDIXES 365

26 Emergency Management 373

Andrea J. Linscott and Natalie Williams-Bouyer

Introduction 373

Emergency Management Plan 374

Purpose or Policy • Hazard Analysis • Incident Management System

Elements of an EMP 376

Emergency Operations Center • Communications • Medical Treatment Areas • Decision to Shut Down Laboratory • Damage Assessment • Evacuation • Personnel Pool • Personnel Care • Locator System • Security • Training • Monitoring and Evaluation

Disasters 379

Fire • Hazardous Materials • Radioactive Material • Utility Failure • Bomb Threat • Active Shooter/Hostage Response • Natural Disasters • Pandemics • Terrorism Threats • Civil Disorder

SUMMARY 382

KEY POINTS 382

GLOSSARY 382

REFERENCES 383

APPENDIXES 384

SECTION V
Financial Management 387

27 Financial Management: Setting the Stage 389

Lynne S. Garcia

Introduction 389

The Hospital Environment 390

Financial Challenges Created by the COVID-19 Pandemic • Operating in the Inpatient Hospital Setting • Operating in the Outpatient Hospital Setting

The Non-Hospital Environment 393

SUMMARY 394

KEY POINTS 394

GLOSSARY 394

ACKNOWLEDGMENT 395

REFERENCES 395

28 Strategic Planning 396

Jonathan R. Genzen and Paul Valenstein

Introduction 396

Business Strategy and Operational Efficiency 396

Developing and Maintaining a Business Strategy: The Strategic Planning Process 397

Structure of the Clinical Laboratory Industry 398

The Testing Market • Concentration of Competitors • Barriers to Entry • Separation of Payor, Purchasing Agent, and Beneficiary • Economies of Scale • Restrictions on Markups and Kickbacks • Powerful Sellers and Buyers • Substitute Products • Unique Economics of Inpatient Care • Conclusions

Competitor Analysis 400

Competitors' Goals • Competitors' Assumptions • Competitors' Capabilities • Interactions of Competitors • Conclusions

Strategic Positions in the Clinical Laboratory Industry 401
What Are Strategic Positions? • Types of Strategic Positions • Strategic Positions of Clinical Laboratories • Conclusions
Implementing the Strategy: Activity Fit 404
What Is Activity Fit? • Activity Fit Involves Trade-Offs
Failure of Strategy 404
Straddling • Growth Trap • Profitability Trap • Hubris
SUMMARY 405
KEY POINTS 406
GLOSSARY 406
REFERENCES 406

29 Human Resource Management in the Laboratory: An Important Component of Financial Management 408
Fred Westenfeld and Michael R. Lewis

Introduction 408
Constraints on Managerial Function 409
The Cardinal Rules for Optimizing Performance 410
Get It Right at the Outset • Expect High Performance • Lead by Example • Involve All Members of the Team • Perceived Fairness Is More Important Than Rigid Equality • Maintain Communication in All Directions • Keep Your Eyes and Ears Open • Act Promptly and Decisively When Necessary • When Problems Surface, Involve Laboratory Leaders and Human Resources as Appropriate
Classic Situations That May Interfere with Optimal Performance 411
The Underperforming Employee • The Overperforming Employee • The Intrusion of Interpersonal Issues • Individual and/or Group Troublemakers • Weakness of the Supervisory Staff
Practical Issues in the Utilization of Human Resources 413
Skill Mix of Staff • Cross-Training and Rotation • Mix of Employment Arrangements • Coverage of Vacations, Holidays, and Routine Shifts • Use of Overtime or External Contract Labor
SUMMARY 414
KEY POINTS 414
GLOSSARY 414
ACKNOWLEDGMENT 415
REFERENCES 415

30 Costs, Budgeting, and Financial Decision Making 416
Geoffrey C. Tolzmann, Richard J. Vincent, and Michael R. Lewis

Introduction 416
Cost Accounting 417
Classification of Costs • Behavior of Costs • Measuring Full Cost • Average versus Marginal Costs • Actual Cost versus Standard Cost • Costing Issues • A Formula for Developing Laboratory Costs • Laboratory Costing Examples
Break-Even Analysis 420
Equipment Purchase • Capitation Contract
Capital Acquisition Concepts 420
Time Value of Money • Depreciation
Budgeting 427
Types of Budgets • The Budgeting Process • Budget Examples
Variance Analysis 430
Financial Statements 434
Financial Ratios
Applications of Financial Tools in the Evolving Laboratory Landscape 437
SUMMARY 437
KEY POINTS 439
GLOSSARY 439
REFERENCES 441

SECTION VI
Coding, Billing, and Charges for Laboratory Services 443

31 Correct Coding of Billable Services in the Clinical Laboratory 445
Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

Introduction 445
Procedure Coding: What Test Procedures Have Been Performed? 446
The CPT System 446
Description • Types of CPT Codes • Modifiers • The Process for Change • Procedure Coding Guidance: The Impact on Reimbursement

Procedure Coding Alternatives 449
Capitated Services 450
Diagnosis Coding: Why Is the Service Being Performed? 450
Inpatient Diagnosis Coding • Outpatient Diagnosis Coding • Other Unique Patient Groups • ICD-CM • SNOMED CT
Service Location 452
Role of CLIA and State Licensing • Revenue Codes
Documentation of Codes 452
Requisition • Claims • Code Mapping
SUMMARY 453
KEY POINTS 453
GLOSSARY 453
REFERENCES 457
APPENDIXES 458

32 Approaches to Billing Laboratory Services 460
Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

Introduction 460
Interactions in the Billing Process 461
Provider Mix • Payor Mix
Terms of Coverage 464
Types of Services • Payment for Services
Logistics of the Billing Process 465
Claim versus Invoice Submission • Invoice Billing • Claim Billing
Fee-for-Service Arrangement Billing 466
Capitated Arrangement Billing 466
Value-Based Pay for Performance 466
SUMMARY 466
KEY POINTS 467
GLOSSARY AND APPENDIXES 467
REFERENCES 467

33 Charges and Fees for Laboratory Services 468
Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

Introduction 468
Calculating Costs and Charges 468
Determining Costs • Setting Charges
Determining Payment Amounts 469
Fee Schedules • Medicare Clinical Laboratory Fee Schedule • Fee Setting for New Codes on the CLFS • The Medicare Physician Fee Schedule • Other Fee Schedules • Capitated Payments
Keys to Success in Reimbursement 472
Retrospective Payment • Prospective Payment • Value-Based Payment
SUMMARY 472
KEY POINTS 473
GLOSSARY AND APPENDIXES 473
REFERENCES 473

SECTION VII
Reimbursement, Compliance, and Profitability 475

34 Rules and Regulations in Reimbursement 477
Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

Introduction 477
General Criteria 478
Basic Rules 478
Procedure Code Edits 479
Basic Edits • National Correct Coding Initiative • Mutually Exclusive Codes • Comprehensive/Component Edits • Medically Unlikely Edits • Add-On Code Edits • Appropriate Use Edits
Conditions of Coverage 481
Medical Necessity • National Coverage Determination • Local Coverage Determination • Medicare Coverage Database • Screening Tests • Experimental Testing • Administrative Policies
Special Coverage Conditions 484
End-Stage Renal Disease • Skilled-Nursing Facility • Ambulatory Payment Classifications • Inpatient Payment Classifications • Three-Day Window • Date of Service Rule • Other Private-Payor Rules
Remittance Advice Review 485
Beneficiary Documents • Provider Documents • Auditing Remittance Advice
SUMMARY 485
KEY POINTS 486
GLOSSARY 486
REFERENCES 489
APPENDIXES 490

35 Reimbursement Compliance 492

Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

Introduction 492
Improper Payments 493
Program Integrity 494
Authority for Program Integrity • Activities in Program Integrity
Payor Integrity 497
Prepayment Review • Postpayment Review
Laboratory Provider Integrity 497
The Seven Essential Elements • Specific Areas of Concern
Coding and Billing Issues 498
CPT Coding • Modifiers • ICD-CM Coding • The Requisition • Special Ordering Situations
Medical-Necessity Issues 501
Record Retention 501
Marketing Practices 501
Pricing and Inducements • Ordering Provider and Patient Communication
Fraud Alerts and Advisory Opinions 502
Auditing and Monitoring 502
Response to Possible Fraud or Abuse 502
Laboratory Examples of Fraud and Abuse 503
SUMMARY 503
KEY POINTS 504
GLOSSARY AND APPENDIXES 504
REFERENCES 504

36 Determination of Profitability 506

Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

Introduction 506
Pitfalls in Cost Accounting 507
Laboratory Profitability 507
Balance Sheets • Income Statements • Cash Flow Statements
Key Indicators 508
Key Income Indicators • Key Expense Indicators
Institutional Profitability 509
Human Profitability 510
Laboratory Value 510
SUMMARY 511
KEY POINTS 511
GLOSSARY AND APPENDIXES 511
REFERENCES 511

SECTION VIII
Outside Marketing and Expansion 513

37 Hospital-Based Laboratory Outreach 515

Richard Adams, Daniel Kelly, and Lynne S. Garcia

Introduction 515
Considering an Outreach Program 515
Administrative Interest • Exploring the Market • Strategic Plan • Business Plan • Sales Plan
Commitment from All Relevant Parties 522
Feasibility Report • Philosophical Understanding • Service and Financial Support
Implementing the Outreach Program 523
People • Processes • Facilities • Equipment • Supplies
Outreach Indicators 523
Growing the Outreach Program 523
Assessment • Client Needs
SUMMARY 524
KEY POINTS 524
GLOSSARY 524
ACKNOWLEDGMENTS 526
REFERENCES 526

38 Finance and Decision Making in Outreach 527

Ziad Peerwani

Introduction 527
The Clinical Laboratory as a Business • The Phases of the Growth Curve
Decision Making in Laboratory Outreach Management 528
Types of Costs 529
Direct and Indirect Costs • Fixed, Variable, and Semifixed Costs • Unit Costs • Additional Cost Concepts for Decision Making • Characteristics of Laboratory Costs • Microcosting • Beyond the Laboratory Test Cost
Levels of Decision Making in Outreach Operations 532
Menu: To Test or Not To Test • Operation: To Perform In-House or Send Out • Capital: Whether To Acquire New Equipment • Financing Capital: To Lease or Buy Equipment
Financial Considerations in Outreach 536
Role of Metrics-Based Decision Making • Realization Rate • Direct Client Billing and Accounts Receivable

SUMMARY 539
KEY POINTS 539
GLOSSARY 539
ACKNOWLEDGMENT 542
REFERENCES 542
APPENDIXES 543

39 Outreach: Obstacles to Hospital Outreach and Enhancing Customer Satisfaction 550

Beth H. Deaton

Introduction 550
Making Organizational Changes 550
Centralize Work • Place Laboratory Management on Off Shifts
Give Outreach Its Due 551
Make Outreach High-Profile • Manage Outreach as a Business, Not a Department
Information Technology Changes 551
Hospital Systems versus Separate Systems • Non-Staff Physicians • Connectivity • Patient Registration and Accounting • Populating the Patient Record • Physician Office Connectivity
Meeting the Needs 553
Capital • FTEs
Hospital versus Outreach Contracting 554
Defining Insurance Plans • Contracting • Acceptance of Payors
Failure to Understand Financial Implications and Requirements 554
Unrelated Business Income Tax • Other Taxes
Understanding the Hospital's Point of View 554
Lower Cost per Test • Make Money
Translating Hospital and Laboratory Compliance for an Outreach Operation 555
Physician Communication • Medicare Secondary Payor Questionnaires • Physician Acknowledgments • Advance Beneficiary Notices • Requisition Design • Pricing • Add-On Tests • National and Local Coverage Policies • Sanctioned Physicians • Contracts • Audits and Reviews • Participation and Cooperation • PAMA—Protecting Access to Medicare Act • Free Lunch and Giveaways
Enhancing Customer Satisfaction: Communication 558
Newsletter • Marketing and Sales Team • Website
Social Media and System-Developed Communication 559
Customer Satisfaction Assessment 559
Surveys • Problem Reporting and Resolution
Couriers: The First Line 561
Insource versus Outsource for Couriers
Client Services 562
Access to Draw Sites and Patient Service Centers 562
Building and Retaining Your Client Base 563
Leverage the Continuum of Care • Keep Asking Why • Follow Up When Clients Leave
Professional Marketing and Sales Personnel 563
Commission Plans • Reports • Prepackaged Information
Technical Expertise Accessibility 564
Accounts That Require Special Care 564
Nursing Homes • Drug Accounts • Home Health Agencies • Veterinary Laboratory Services
Define Service Area and Services 565
Range of Services • The Importance of Standardization
SUMMARY 567
KEY POINTS 567
GLOSSARY 567
REFERENCES 568
APPENDIXES 569

SECTION IX
Clinical Trials and Evidence-Based Laboratory Medicine 573

40 The Current State of the U.S. Food and Drug Administration Process and Regulations for Diagnostic Laboratory Assays 575

Donna M. Wolk, Natalie N. Whitfield, and Fran White

Introduction 575
Background: The FDA Processes for Classification and Assessment of New IVDs 576
Premarket Approval • Premarket Notification 510(k) and 510(k) Review • Alternate Application Submission Approaches • The "Presubmission (Q-Sub)" Process • The Expedited Review
The Emergency Use Authorization Act 580
Miscellaneous FDA Requirements 580

Establishment Registration • Medical Device Listing • Good Manufacturing Practices (GMPs) and Quality System Regulations (QSRs) • Quality Control
Automated Laboratory Assays 580
Postmarket Review 581
Limitations Inherent to Current FDA Processes 581
SUMMARY 581
KEY POINTS 582
GLOSSARY 582
REFERENCES 582

41 The Clinical Trial Laboratory: Research Compliance for Clinical Microbiologists 584
Donna M. Wolk, Amanda M. Styer, and Natalie N. Whitfield

Introduction 584
Organizational Resources for Funded Clinical Research in Laboratory Medicine 585
Office of Sponsored Projects • Office of Research and Contract Analysis
Compliance with Human Subject Regulations 586
Background for Human Subject Regulations • Regulatory Requirements for HSPPs • Human Subject Research: Classifications Based on Risk • Human Subject Training Requirements and Site Authorization • Informed Consent • Special Populations • Continuing Review by the IRB • Record Retention for HSPPs
Compliance with HIPAA 588
Compliance with Conflict-of-Interest Policies 589
Intellectual Property Considerations 590
GLP and GCP Regulations 591
Sponsor Responsibilities • Study Director Responsibilities • Quality Assurance Office: Organization, SOPs, Inspections, and Reporting Data • GLP Background • Equipment and Validation of Equipment • Standard Operating Procedures • Reagents and Solutions for Tests and Controls • Final Research Reports
SUMMARY 592
KEY POINTS 592
GLOSSARY 593
REFERENCES 593
APPENDIX 594

42 Clinical Trials and Evidence-Based Research in the Clinical Laboratory 595
Donna M. Wolk and Natalie N. Whitfield

Introduction 595
Types of Research Studies 596
Observational Studies • Mechanistic Studies • Therapeutic Studies • Large-Scale Clinical Trials • Meta-Analyses and Systematic Reviews
Translational Research 597
Sequence of Investigation 597
Study Design • Hypothesis Generation • Sampling the Population • Deciding on Sample Size, Measurements, and Endpoints • Feasibility • Confounding Variables and Bias • Human Subject Protection • Collecting and Storing Data • Data Analysis and Conclusion Formulation
Traditional Biostatistics 599
Descriptive Statistics • Inferential Statistics: Issues for Medical Devices • Challenges for Diagnostic Studies
Other Research Considerations 601
Systematic Reviews and Laboratory Medicine Best Practices 601
Evidence-Based Laboratory Medicine • Laboratory Medicine Best Practices Initiative
Using Machine Learning for Prediction 603
SUMMARY 603
KEY POINTS 603
GLOSSARY 604
REFERENCES 604
APPENDIXES 606

SECTION X
Defining and Measuring Standards for Success 607

43 Benchmarking and Performance Monitoring for the Clinical Laboratory 609
Lauren N. Pearson and Michael R. Lewis

Introduction 609
Why Benchmark? 610
Types of Benchmarking 611
General Approach to Benchmarking and Performance Monitoring 612

Prioritization • Metrics Selection • Data Collection and Analysis • Development and Implementation of Plans

Interpretation of Benchmarking and Performance Monitoring Data 613

Interpretation of External Benchmarking Data • Interpretation of Internal Benchmarking Data • Data Interpretation in the Context of the Laboratory's QMS and Specific Quality Indicators That Are Evaluated

Challenges in Executing Benchmarking and Performance Monitoring 614

The Problems of Comparability and Selection Bias • The Problem of Cost Accounting • Selection of Indicators for Benchmarking and Performance Monitoring • Effects of the COVID-19 Pandemic Render Many Data from 2020–2021 Unhelpful for Comparisons

Measuring Laboratory Performance in the Broader Clinical Setting 616

Assessments for Patient Safety • Effect of Value-Based Payment Models (and Other Contemporary Influences) • Linkage of Payment to Measures of Quality • Laboratory-Related Standards in Broader Accreditation Programs

The Unattained Ideal: A Global Laboratory Benchmarking Scorecard Spanning Cost, Quality, and Operational Measures 618

SUMMARY 618

KEY POINTS 618

GLOSSARY 619

ACKNOWLEDGMENTS 620

REFERENCES 620

APPENDIX 622

44 Test Utilization and Clinical Relevance 626

Michael L. Wilson, Gary W. Procop, and L. Barth Reller

Introduction 626

Evaluating Potential and Real Problems 627

Clinical Relevance • Cost-Effectiveness Analysis, Cost-Benefit Analysis, and Cost-Utility Analysis

Documenting the Extent of the Problem 628

Literature Review • Centralized Studies • Local Data

Laboratory-Based Approaches to Control 629

Newsletters • Policy Changes • Personal and *Ad Hoc* Communication • EMR-Based Limits and Restrictions on Test Ordering • EMR-Based Feedback in Reports

Institution-Based Approaches to Control 631

Working with Providers • Formal Protocols Validated by Provider Leadership • The Concept of a Test Formulary • Using Major Events To Effect Change

What Works and Doesn't Work: How To Take the First Steps 633

Putting It All Together 635

Base Policy Approaches and EMR-Based Controls on Evidence-Based Medicine • Track Results • The Plan, Do, Study, Act Model • The Future: Better Teaching and Training

SUMMARY 636

KEY POINTS 636

GLOSSARY 636

REFERENCES 637

SECTION XI
The Future of Clinical Laboratories 639

45 The Future of Pathology and Laboratory Medicine: Political, Social, Economic, and Regulatory Impacts 641

Lisa M. Stempak and Mark Rodgers

Introduction 641

The Current Environment of Healthcare 641

Current Regulations 642

CLIA '88 • HIPAA • OSHA Standards for Occupational Exposure to Blood-Borne Pathogens • Physician Self-Referral Law (Stark Law)

Liability Considerations 645

Bioterrorism and Emerging Highly Infectious Diseases 645

Recent History • Future Impact

Long-Term Effects: Legislation, Regulation, and Accreditation 646

Quality, Value, and Patient Safety • Financial Considerations of the Patient Safety Movement • The "No Surprises" Act

Issues Affecting Academic Laboratories and Research 647

Financial, Regulatory, and Staffing Concerns • Biorepositories, Restrictions on Use of Human Tissues, and Stem Cell Research

SUMMARY 648

KEY POINTS 649

GLOSSARY 649

REFERENCES 650

APPENDIX 651

46 The Future of the Clinical Scientist Workforce 652

I. J. Frame, Donna Gaffney, and Jana Bagwell

Introduction 652
A Profession Defined by a Pandemic 653
Educating the Workforce: Challenges and Opportunities 653
Emerging Roles of the Clinical Scientist 654
Emerging Laboratory Management Considerations with the Clinical Scientist
SUMMARY 657
KEY POINTS 658
GLOSSARY 658
ACKNOWLEDGMENTS 658
REFERENCES 658

47 Electronic Health Records and Their Implications and Opportunities for Laboratories 660

Roger L. Bertholf

Introduction 660
Electronic Health Records 661
Definition and Components • Status of EHR Use
Federal Regulations Related to EHRs and Their Implications for Laboratories 662
Meaningful-Use Requirements Directly Relevant to Laboratories • EHR Certification • Certification Criteria and Standards Most Relevant to Laboratories
Concerns and Implications for Laboratories Related to Increased Use of EHR Systems 664
Potential Consequences • Laboratory Reports • "Order Set" Challenges • Information Overload • Formatting Incompatibilities
Results Management 666
Laboratory Report Components • Laboratory Report Retrieval • Cumulative Laboratory Results • Laboratory Data Display Issues • Validation of EHR Laboratory Report Displays • Physician Alerts • Laboratory Test Result Delivery in an Integrated Healthcare Network
Computerized Provider Order Entry 667
Introduction • CLIA '88 Required Laboratory Test Request Elements • Appropriate Choice of Individual Laboratory Test Names
EHR-LIS Interfaces 668
Technical Aspects of Interfaces: HL7 and LOINC • Operational Challenges for Laboratories with LIS-EHR Interfaces
Tactics for Working with EHR Support Staff 670
Laboratory Involvement in EHR Selection and Implementation 670
SUMMARY 671
KEY POINTS 671
GLOSSARY 671
ACKNOWLEDGMENT 672
REFERENCES 672

48 Current Trends in Instrumentation and Technology: A Look toward the Future 674

Patrick B. Kyle and Lauren McVoy

Introduction 674
Hematology 677
Automated Enumeration of Cell Populations • Molecular Testing
Chemistry 679
Advances • Laboratory Computerization • Laboratory Automation
Microbiology 680
Advances • Microorganism Identification • Molecular Microbiology
Blood Transfusion and Coagulation 681
Coagulation and Thromboelastography • Inventory Tracking and Use
Point-of-Care Testing 682
Computerization • Rapid Assays • Developments during COVID-19
Molecular Diagnostics 683
Real-Time PCR
Outlook for the Future 683
Driving Forces • Device Miniaturization
SUMMARY 684
KEY POINTS 684
GLOSSARY 685
REFERENCES 686

49 The Future Practice of Laboratory Medicine 690

Christopher Zahner and Peter McCaffrey

Introduction 690
Trends Impacting the Field of Clinical Pathology 691
Difficulty in Finding Laboratory Staff Workforce • Computation • Increasing Patient Access • Going Remote
Response of the Pathology Department to Recent Trends 692

Informatics and Artificial Intelligence • Automation • Laboratory Consultation • Remote Ready
Laboratory Principles To Live By 696
Accuracy and Reliability • Scalability • Coordination • Flexibility
SUMMARY 697
KEY POINTS 698
GLOSSARY 698
REFERENCES 698

SECTION XII
Pandemics and Healthcare Institutions 701

50 Epidemics and Pandemics: Lessons from the Past, Concerns for the Future 703
Charles S. Bryan

Introduction 703
Some Basics of Epidemiology 704
The Importance of Zoonoses 704
Epidemics and Pandemics as Four-Act Plays 704
Act One: Progressive Revelation • Act Two: Management of Randomness • Act Three: Negotiation of a Public Response • Act Four: Subsidence and Retrospection
Lessons from Selected Epidemics and Pandemics from Antiquity through HIV/AIDS 704
Epidemics of Antiquity • Plague • Smallpox • Yellow Fever • Cholera • Influenza • HIV/AIDS
Coronaviruses and COVID-19 709
Coronaviruses • Severe Acute Respiratory Syndrome • Middle East Respiratory Syndrome • COVID-19 as a Four-Act Play
The Anthropocene and Future Epidemics and Pandemics 712
The Anthropocene Epoch • Threats Posed by Currently Known Infectious Agents • Potential Threats from Novel Pathogens
Roles of Laboratories 712
SUMMARY 713
KEY POINTS 713
GLOSSARY 713
REFERENCES 716

51 One Health in Pandemic Planning, Prevention, and Response 717
Craig Stephen

Introduction 717
Pandemics in the Anthropocene: the Call for Transformative Change 718
What Is One Health? 718
One Health Thinking for Pandemic Risk Management 719
One Health Intelligence
Operational Impediment and Opportunities 721
Confronting the Reality of Complexity 722
Being Multifaceted • Being Multisolving • Being Adaptive
SUMMARY 723
KEY POINTS 723
GLOSSARY 724
REFERENCES 724

52 Pandemic Planning: Roles of Clinical and Public Health Laboratories 727
Robert T. Ball, Jr., Joseph F. John, Jr., and Michael G. Schmidt

Introduction 727
Perspectives from Previous Pandemics and COVID-19 728
Investments in Novel Therapeutics • A Progression in Understanding the Evolution of Pandemics • Pandemic Fatigue • Role for Immunology-Based Diagnostics • Early Recognition—SARS-CoV-2 and Its Global Spread • Emergence of COVID-19 and the Response of Taiwan • Effective Mitigative Solutions for COVID-19 in Taiwan • Paradigm Shift: Roles for Big Data in Pandemic Management
Challenges Facing Clinical and Public Health Laboratories 732
Roles of Laboratories • Advances in Diagnostic Technology • Genomics and Its Role in Mitigating Pandemics • Microbes to Pandemic Agents: Laboratory Mobilization
Pandemic Planning: Partnerships for the Future 734
Collaboration between Clinical and Public Health Laboratories • Global Surveillance • Economic Costs • Vaccines • Vaccine Hesitancy • Collaboration and Linkage of Laboratories to Incident Commands • The Next Pandemic for Humankind
SUMMARY 738
KEY POINTS 739
GLOSSARY 739
REFERENCES 740

53 Laboratory Preparedness 744

Deirdre Church

Introduction 744

Lessons Learned from the Laboratory Response to COVID-19 745

Organization of Healthcare and Laboratory Systems • Implementing New Tests and Surge Capacity • Supply Chains • Appropriate Outbreak Testing • Quality and Staffing • Regulatory Requirements

Framework for Laboratory System Preparedness 751

Manufacturing and Distribution • Executive Plan • Human Resources Development • Health Informatics • Specimen Logistics and Transportation • mHealth

Laboratory Networks and Biosafety 756

Future Directions 757

SUMMARY 758

KEY POINTS 759

GLOSSARY 759

REFERENCES 760

INDEX 763

Contributors

Richard Adams
Cleveland Clinic, Cleveland, OH 44195

Sarah Ampomah
Point-of-Care Testing, Froedtert Hospital, Froedtert and the Medical College of Wisconsin, Milwaukee, WI 53226

Christina E. Anderson
Virginia Commonwealth University, Pathology, Richmond, VA 23298

Kristine Apfeld
Point-of-Care Testing, Community Physicians and Froedtert Hospital, Froedtert and the Medical College of Wisconsin, Milwaukee, WI 53226

Steven M. Armstrong
Vitalant Reference Laboratories and Transfusion Medicine, Pittsburgh, PA 15212

Gabriel E. Ayala
University of Calgary, Cumming School of Medicine, Calgary, Alberta T2N 4N1, Canada

Jana Bagwell
University of Mississippi Medical Center, Medical Laboratory Science Program, School of Health Related Professions, Jackson, MS 39216

Robert T. Ball, Jr.
Medical University of South Carolina, Medicine - Division of Infectious Diseases and Department of Public Health Sciences, Charleston, SC 29425

Vickie S. Baselski
University of Tennessee Health Science Center, Department of Pathology, Memphis, TN 38163

Lindsay Ann Bazydlo
University of Virginia, Pathology, Charlottesville, VA 22910

Kathleen G. Beavis
University of Chicago, Department of Pathology, Chicago, IL 60637

Katharine R. Becker
PLB Ventures, Carson City, NV 89703

Roger L. Bertholf
Houston Methodist Hospital, Department of Pathology and Genomic Medicine, Houston, TX 77030

James W. Bishop
New Mexico State University, Department of Management, Las Cruces, NM 88003

Cameron A. Brown
Harris Health Ben Taub Hospital, Department of Pathology and Laboratory Medicine, and Baylor College of Medicine, Department of Pathology & Immunology, Houston, TX 77030

Charles S. Bryan
University of South Carolina School of Medicine, School of Medicine Library, Columbia, SC 29208

Lakshmi Chandramohan
NeoGenomics Laboratories, Pharma Molecular Division, Houston, TX 77085

Deirdre L. Church
University of Calgary, Calgary Laboratory Services, Calgary, Alberta T2KL 2K8, Canada

Beth H. Deaton
Inova Health Care Laboratories, Fairfax, VA 28132

Melinda L. Doherty
(Formerly) Baylor Scott & White Health Laboratory Information Systems, Dallas, TX 75246

James J. Dunn
Texas Children's Hospital, Department of Pathology, and Baylor College of Medicine, Department of Pathology & Immunology, Houston, TX 77030

I. J. Frame
University of Mississippi Medical Center, Department of Pathology, Jackson, MS 39216

Donna Gaffney
Parkland Health, Laboratory Services, Dallas, TX 75235

Lynne S. Garcia
LSG & Associates, 512 12th Street, Santa Monica, CA 90402

Jonathan R. Genzen
University of Utah / ARUP Laboratories, Pathology, Salt Lake City, UT 84108

Elizabeth A. Godbey
Department of Laboratory Medicine and Pathology, Mayo Clinic Florida, Jacksonville, FL 32224

Mark G. Hanly
SEPA Labs, Pathology, Brunswick, GA 31525

David S. Hefner
Wayne State University, Office of the Vice President of Health Affairs, Bradenton, FL 34207-5605 (Retired)

Marianna L. Hofmeister
University of Calgary, Community Health Sciences, Calgary, Alberta T2N 1N4, Canada

Joseph F. John, Jr.
Lowcountry Infectious Diseases and MUSC Department of Medicine, Division of Infectious Diseases, Charleston, SC 29414

Daniel Kelly
Cleveland Clinic, Marketing, Cleveland, OH 44195

Anthony S. Kurec
SUNY Upstate Med University, Pathology, Chittenango, NY 13037

Patrick B. Kyle
University of Mississippi Medical Center, Pathology, Jackson, MS 39047

Sandra L. Lamm
Virginia Commonwealth University, Transfusion Medicine, Richmond, VA 23298

Michael R. Lewis
Banner MD Anderson Cancer Center, Pathology, Gilbert, AZ 85234

Andrea J. Linscott
Ochsner Health, Department of Pathology and Laboratory Medicine, New Orleans, LA 70121

Anne Marsden
San Juan Capistrano, CA 92675

Stephanie Maynard-Patrick
University of Illinois-Springfield, Department of Management, Springfield, IL 62703

Peter McCaffrey
University of Texas Medical Branch, Pathology, Galveston, TX 77555

Lauren McVoy
Memorial Sloan Kettering Cancer Center, Pathology and Laboratory Medicine, New York, NY 10065

Patti Medvescek
PmedvescekLLC, Consulting, 3007 Earl Drive, Indianapolis, IN 46227

Christopher Naugler
University of Calgary, Pathology and Laboratory Medicine, Diagnostic and Scientific Centre, Calgary, Alberta T2L 2K8, Canada

Elise A. Occhipinti
Ochsner Health, Department of Pathology and Laboratory Medicine, New Orleans, LA 70121

Christa P. Pardue
HealthTrust, Clinical Operations, Nashville, TN 37203

Lauren N. Pearson
University of Utah, Pathology, Salt Lake City, UT 84112

Ziad Peerwani
Cleveland Clinic, PLMI, Cleveland, OH 44106

Gary W. Procop
American Board of Pathology, Tampa, FL 33609

Glenn Ramsey
Northwestern University, Pathology, Chicago, IL 60611

L. Barth Reller
Duke University School of Medicine, Departments of Pathology and Medicine, Durham, NC 27710

Paula Revell
Pathology & Immunity and Pediatrics, Baylor College of Medicine, Houston, TX 77030

Mark Rodgers
University Hospitals Health System, Department of Pathology, Chardon, OH 44024

Susan D. Roseff
Department of Pathology, VCU School of Medicine, Richmond, VA 23298-0662

Denise E. Russell
Consultant, Risk Management and Health Law, Houston, Texas

Michael G. Schmidt
Medical University of South Carolina, Microbiology and Immunology, Charleston, SC 29425-0504

Dow Scott
Loyola University Chicago, Institute of Human Resources and Employment Relations, Quinlan School of Business, Chicago, IL 60611

Ji-Yeon Seok
New Mexico State University, Department of Management, Las Cruces, NM 88003

Amy Shahtout
Trabuco Canyon, CA 92679

Laura Smy
Department of Pathology & Laboratory Medicine, Medical College of Wisconsin, Milwaukee, WI 53226

Emily A. Snavely
University of Virginia Health System, Pathology, Charlottesville, VA 22908

Fran Sorrell
American Esoteric Laboratories, Memphis, TN 38134

Lisa M. Stempak
University Hospitals Health System, Department of Pathology, Cleveland, OH 44106

Craig Stephen
McEachran Institute, Nanoose Bay, British Columbia, Canada V9P 9B3

Amanda M. Styer
Geisinger, Laboratory Medicine Research, Danville, PA 17820-1930

Molly Thieme
Point-of-Care Testing, Community Physicians, Froedtert and the Medical College of Wisconsin, Milwaukee, WI 53226

Geoffrey C. Tolzmann
Essex, Vermont (Retired)

Paul Valenstein
Berkeley, California (Retired)

Richard J. Vincent
University of Vermont Health Network, Burlington, VT 05401

Alice S. Weissfeld
Microbiology Specialists, Inc., Houston, TX 77054

Paul Wesolowski
Office of the Chief Operating Officer, Virginia Commonwealth University Medical Center, Richmond, VA 23298

Fred Westenfeld
Mayo Clinic, Laboratory Medicine and Pathology, Jacksonville, FL 32224

Fran White
MDC Associates, Medical Devices Regulatory Consulting, Beverly, MA 01930

Natalie N. Whitfield
Inflammatix, Inc., Medical Affairs, Burlingame, CA 94010

Natalie Williams-Bouyer
University of Texas Medical Branch at Galveston, Department of Pathology, Galveston, TX 77555-0419

Michael L. Wilson
Denver Health Medical Center, Department of Pathology and Laboratory Services, Denver, CO 80204

Donna M. Wolk
Geisinger, Diagnostic Medicine Institute, Department of Laboratory Medicine, Danville, PA 17822-1930

Kenneth E. Youens
Baylor Scott & White Health, Pathology and Laboratory Medicine, Temple, TX 76502

Christopher Zahner
University of Texas Medical Branch, Pathology, Galveston, TX 77555

Preface

The current environment for laboratory medicine and pathology continues to undergo dramatic transformation, which is influenced by significant changes in the legislative, regulatory, reimbursement, technologic, sociologic, economic, communication, and business sectors. The practice of all aspects of medicine and allied healthcare requires new approaches and a much broader range of managerial expertise. Areas in which a laboratory director, manager, or supervisor is expected to understand and perform include fiscal and human resources, patient care testing and quality performance issues, and overall accountability to the facility administration. It is very important that individuals working within the healthcare environment learn to hear, speak, and thoroughly understand the operational language of healthcare administration. During the past few years, the fields of laboratory medicine and pathology management have seen many dramatic changes, including those related to quality assurance, communication, data storage and retrieval, point-of-care testing, test management, automation, safety and emergency preparedness (particularly in light of the COVID-19 pandemic), regulatory requirements, information confidentiality, billing and coding requirements, physical space changes, laboratory consolidation, shortage of training programs and trained personnel, competency testing, specimen handling and shipping requirements, decrease in reimbursement, demand for increased productivity, and increased need for consultation and educational initiatives for clients. Reactions to the changes that have occurred in the healthcare environment in recent years are essentially 2-fold: increased efforts to contain costs, and increased demand for appropriate and error-free medical care. Both of these have been influenced by the complex challenges related to the COVID-19 pandemic.

The purpose of this text is to provide comprehensive, practical information and guidelines for healthcare management in the 21st century for laboratory directors; managers; chief technologists; supervisors; trainees in schools of healthcare administration, medical laboratory technology, and other allied health disciplines; those training for leadership positions; and those studying for board or registry certification in management. This book is designed for those who are training to enter these fields and for those who are already actively working in clinical pathology and clinical laboratory management. It contains a comprehensive overview of management principles and how they apply to the clinical laboratory. In-depth analysis of the financial challenges facing clinical laboratories is included, as are discussions on good business practices. There is extensive information on the impact of the regulatory environment on every aspect of clinical laboratory practice, as well as personnel management related to all relevant job classifications. Additional discussions include the changing practice of medicine, managerial leadership, the expanding field of point-of-care testing, enhanced information systems and security/confidentiality requirements, reimbursement compliance, outside marketing and expansion, clinical trials and evidence-based medicine, benchmarking, current trends in instrumentation and technology, enhanced consultation through expanded test result reports, and the future of clinical laboratories. All chapter topics have been extensively updated, particularly including elements from the COVID-19 pandemic, and a comprehensive new section has been added to cover the particular administration and personnel challenges associated with the pandemic.

The authors of these chapters are all practicing laboratorians, many of whom have had extensive "hands-on" experience in all facets of clinical laboratory practice, including both technical and managerial responsibilities. Each section is edited by experienced professionals to include comprehensive coverage, both didactic and practical, of all issues related to clinical laboratory operations.

Extensive laboratory management information is available in one resource and includes practical examples and numerous summary tables to serve as guidelines for relevant documentation. Various management tools are provided, particularly related to personnel, technical, regulatory, and financial responsibilities. This information is relevant for all job levels within the laboratory, as well as for all healthcare management and technical training courses. Each chapter follows the same format, which is designed to flow easily from one section to another. Extensive websites are included that provide additional valuable information related to each chapter.

It is important for readers to understand that there are many different laboratory settings; not every laboratory

will handle managerial responsibilities the same way, nor will every option be applicable to every situation. The key to quality and clinically relevant laboratory management approaches requires a thorough understanding of the pros and cons of each approach and how various options may or may not be relevant for one's particular laboratory size and range of expertise, client base, number and type of patients seen, personnel expertise and availability, equipment availability, educational initiatives, and communication requirements.

The use of product or program names is not intended to endorse specific products or programs or to exclude substitute products or programs. Every effort has been made to ensure accuracy; however, ASM Press and the editors encourage you to submit to us any suggestions, comments, and information on errors found.

Acknowledgments

As editors for the Third Edition of *Clinical Laboratory Management*, we would like to express our thanks to the educators, colleagues, and students who have helped shape our perspectives regarding the field of clinical laboratory and pathology management. As with the first two editions, the aim was to consolidate this information for the benefit of those working in healthcare and to share our knowledge with individuals currently working in laboratory management positions. However, regardless of your position in the healthcare arena, understanding the management challenges and "rules of the game" continues to be beneficial for everyone.

Our special thanks go to the authors for their outstanding contributions. These individuals have extensive work experience in the field and bring this expertise to each chapter. We appreciate the time and energy it took to produce the Third Edition, knowing that all were extremely busy coping with the administrative and personnel challenges associated with the COVID-19 pandemic along with the day-to-day operations within their laboratories.

We would like to thank members of the editorial staff of ASM Press, especially Eleanor Tupper, Melissa Junior, Megan Angelini, Lindsay Williams, Ellen Fox, and Christine Charlip; they are outstanding professionals and contributed extensive support throughout the publication process. With their help, we all managed to complete the task.

Our special thanks go to our families and colleagues for their support, guidance, and advice during this extensive project. This Third Edition was very much a collaborative effort, and we hope the material will prove beneficial to the overall healthcare community.

Lynne S. Garcia
Timothy C. Allen, Vickie S. Baselski,
Deirdre L. Church, Donald S. Karcher,
Michael R. Lewis, Andrea J. Linscott,
Melinda D. Poulter, Gary W. Procop,
Alice S. Weissfeld, and Donna M. Wolk

I

Basic Concepts and the Current Healthcare Environment

(SECTION EDITOR: **Donald S. Karcher**)

1 **Clinical Laboratory Management: Basic Principles and Practices**
Paul Wesolowski and Susan D. Roseff

2 **Regulatory Issues in Laboratory Medicine**
Glenn Ramsey and Christina E. Anderson

3 **The Changing Practice of Medicine**
Elizabeth A. Godbey, Susan D. Roseff, and Denise E. Russell

4 **The Changing Healthcare Environment**
Steven M. Armstrong and Sandra L. Lamm

1

Clinical Laboratory Management: Basic Principles and Practices

Paul Wesolowski and Susan D. Roseff

Management, Leadership, and Administration
A Brief History of Management Concepts
Classical Theory • Behavioral Theory • Quantitative Theory • Operations Management and the Integrated Theory
Decision Making and Problem Solving
What Is Decision Making? • Types of Decisions • Individual versus Group Decision Making • The Problem-Solving/Decision-Making Process
Management Functions
Planning • Organizing • Directing • Controlling • Summary
The Evolving Models of Clinical Laboratories
Centralized Testing • Decentralized Testing
The Basics of Financial Management
Costs • Revenue • Gross versus Net Revenue • Medicare • Managed Care • Budgeting • Operating Budget • Capital Budget • Revenue Cycle: Billing and Collecting
A Brief History of Clinical Laboratory Finances
Management Ethics
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENTS
REFERENCES
APPENDIXES

OBJECTIVES

To familiarize the reader with the concepts of leadership, management, and administration

To define how leadership, management, and administration are similar, are different, and overlap

To place modern management ideas in their historical context

To review the four management functions: planning, organizing, directing, and controlling

To discuss how laboratory models are evolving

To review in general terms the variety of financial management concepts and philosophy

To learn in general terms the process of decision making and how a decision-making style reflects one's leadership style

To define relevant economic issues that influence the delivery of healthcare services and their significance to the practice of laboratory medicine

Management is the art of getting things done through people.

Mary Parker Follett

Management, Leadership, and Administration

Leadership and management are terms that are often considered synonymous. It is essential to understand that leadership is a critical part of effective management. Managers are in constant action. Almost every study of managers in action has found that they switch frequently from task to task, changing their focus of attention to respond to issues as they arise, and engaging in a large volume of tasks of short duration.

As a crucial component of management, leadership behavior stresses building an environment in which each employee develops and excels. Leadership is defined as the potential to influence and drive the group's efforts towards the accomplishment of goals. A manager must have the traits of a leader. Leaders develop and begin strategies that build and sustain competitive advantage. Organizations require robust leadership and robust management for optimal organizational efficiency (Appendix 1.1).

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch1.

Leadership differs from management; while managers lay down the structure and delegate authority and responsibility, leaders provide direction by developing the organizational vision, communicating it to the employees, and inspiring them to achieve it. Management includes focus on planning, organizing, staffing, directing, and controlling activity; leadership is mainly a part of directing the function of management. Leaders focus on listening, building relationships, teamwork, inspiring, motivating, and persuading the followers. A leader gets his/her authority from his/her followers; a manager gets his/her authority by virtue of his/her position in the organization. Managers follow the organization's policies and procedures; leaders follow their own instincts. Management is more of a science, as managers are exact, planned, standard, and logical. Leadership is an art.

In an organization, if managers are required, then leaders are essential. Management deals with the technical dimension of an organization or the job content; leadership deals with the "people" aspect in an organization. Management measures/evaluates people by their individual actions, past records, and present performance; leadership sees and evaluates individuals as having potential for things that cannot be measured, i.e., it deals with future and the performance of people if their potential is fully extracted. Management is reactive, leadership is proactive. Management is based more on written communication, while leadership is based more on verbal communication (Appendix 1.1).

Organizations that are over-managed and under-led do not perform up to their potential. Leadership, accompanied by management, sets a new direction and makes efficient use of resources to achieve their goals. Both leadership and management are essential for individual as well as organizational success.

With leadership and management defined, "administration" will be discussed. Is this something different from the above or merely a different word for what managers and leaders do? Defined by Merriam-Webster, *administer* lists first, "to manage or supervise . . ." and later, "to furnish a benefit" (1). Based on that second definition, it is possible to think of administration as an action apart from leadership and management, focusing effort on assistance and service, as opposed to the specific acts that a manager or leader might undertake. A manager and/or leader may have as his charge the requirement to serve others. But that becomes a task specific to that individual rather than a general charge to managers at large.

One of the primary definitions of *administrator* refers to government and public sector affairs (1). Administration, by that definition, becomes a public service job, much like one would see in academia or healthcare. Thus, administrators might, in fact, do different things than managers. This is to say, administration is a subset of management. Administrators do all those things that make one a manager. Administrators have a public service requirement and commitment that would not necessarily be found in the portfolio of all working managers.

We have quickly covered some of the basics of leadership and management and touched briefly on administration. More information on leadership can be found in chapter 5 of this volume.

A Brief History of Management Concepts

The history of management can be categorized into four periods: classical theory, behavioral theory, quantitative theory, and integrated theory.

Classical Theory

The earliest perspective on management and management theory was described by a group called classical theorists. Most notably, this group includes Frederick Taylor and his work on scientific management theory. Additionally, this group includes Henri Fayol and his work, referred to as administrative management, and Max Weber and his research into the nature of bureaucracy. This group and others laid the foundation for management theory, in part by identifying the key managerial processes and the skills a manager needs to succeed. Perhaps most importantly, their work made management a valid subject for academic inquiry.

Taylor was one of the first people to create a science of management (2). He is best known for his attempts to systematically analyze human behavior at work. His model was a machine made of cheap interchangeable parts. Taylor attempted to do to complex organizations what engineers had done to machines. This involved breaking down each task into the smallest identifiable unit and then figuring out the best way to do that part of the job. He felt that productivity would improve if each aspect of work was carefully studied and the alternatives facing each worker were restricted. He was correct but has been criticized for dehumanizing the workplace and reducing human beings to little more than machine cogs in the production process. But, the principles of scientific management had been well defined:

1. Describe and break down each task into its smallest component and study that task until the best way to do that task is fully defined.
2. Remove uncertainty and alternatives facing each employee and reward productivity with incentives.
3. Use experts—for example, industrial engineers—to define optimal work outputs and plan for optimal results.

Fayol identified the four basic management functions: planning, organizing, leading, and controlling. His work

focused on management more than tasks and production. He identified 14 principles of management, universal truths he thought could be taught (reference 3, p. 20–41), namely, division of work, authority, discipline, unity of command, unity of direction, subordination of individual interest, remuneration, centralization, chain of command, order, equity, stability, initiative, and esprit de corps.

We will not discuss each principle individually, leaving that for the reader to explore. These are still taught as the basics of management, and Fayol's work remains as pertinent today as it did early in the 20th century.

Max Weber embellished the scientific management theories with his views on bureaucracy and organizational theory (4). He focused on dividing organizations into hierarchies and establishing lines of authority and control. He suggested that organizations develop comprehensive and detailed standard operating procedures for all routine tasks. Where Fayol, before him, had laid out his principles of management, Weber identified the core elements of the new organization, i.e., the bureaucracy: formal rules and behavior defined by those rules, uniformity of operations despite changes in personnel, division of labor based on functional specialization, rational allocation of tasks, impersonal orientation, membership that constitutes a career, promotion based on technical competence, employment based on merit, tested qualifications, legally defined and prescribed lines of authority, limited discretion of senior management and officers, specific spheres of competence, and legally based organizational tenure (4).

Weber believed that emphasizing order, rationality, and uniformity would lead to more equitable treatment of the workers. He is faulted in some circles for his authoritarian views and the concept that authority is position-based and not focused on the individual. Clearly, however, his work moved beyond that of Taylor and Fayol and laid the groundwork for the next generation of management thought.

Behavioral Theory

The second category of management concepts is behavioral theory. Despite the economic progress brought about by the implementation of scientific management, as noted above, many critics were pointing to the dehumanization of the workplace. Labor and management conflict ensued, and worker apathy and boredom were believed to be widespread. These concerns, along with developments in the field of psychology and economics, brought to the forefront challenges to the assumptions of the scientific management school.

The Hawthorne studies at a Western Electric plant in Illinois were a straightforward attempt to determine if there was a relationship between the work environment and productivity (5). In one famous experiment, the illumination in one work area was adjusted and another area acted as a control. The productivity between the two groups was compared. Curiously, the productivity of each group increased, challenging the assumption that mere physical environmental changes were the key. Elton Mayo and his associates, who performed the experiments, believed the increase in productivity was a result of the increased attention paid to both sets of workers. Other studies performed by Mayo illustrated that workers will perform at a level informally set by the work group and that external management often will have little impact on those decisions. Thus, Mayo concluded that social processes play a major role in determining worker attitudes and behavior, far from the previously accepted notions that workers and tasks could be parsed out like parts of a machine (5). This led to the development of the human relations movement, which is based on the idea that a manager's concern for his workers will lead to increased worker satisfaction and improved performance.

Shifting the focus from strictly organizational needs, the human relations movement sought to bring the wants and needs of the individual worker into the discussion. American psychologist Abraham Maslow devised his six-level hierarchy of needs that, according to his theory, determines human behavior (6). He ranked them as follows: physiological, security and safety, love and feelings of belonging, prestige and esteem, self-fulfillment, and curiosity and the need to understand.

As one level of needs is met, we can work toward meeting the next level. If management wants solid, productive employees, motivated to work at their best, then every individual must be compensated and supported to the point where their basic needs are fulfilled and no longer seem to be a concern. Crucial, of course, is the understanding that what would fulfill one person may not address another's perceived needs. Hence, individual attention to each worker is a requirement for management to succeed.

Douglas McGregor developed his own theory of motivation and management, which is referred to as **theory X and theory Y** (7). In short, behind every management decision and action are assumptions about human nature and human behavior. Theory X ascribes to the more negative and perhaps Taylorist concept that people need direction and control and are incapable of taking responsibility. Individuals all need financial inducements and threats to make them work. Theory Y, on the other hand, presumes that people want their work to be fulfilling and that they seek self-respect and self-development. Theory Y suggests that work is a natural human enterprise and that the average person does not dislike work. Effort on the job need not come as a result of threats, but rather results if the individual is committed to the organization and its objectives. Satisfaction on the job and self-actualization can be directed toward the objectives of the organization. Additionally, theory Y proponents accept that imagination, ingenuity,

and creativity are not restricted to a narrow group within the organization but are widespread and only need to be tapped.

Both behaviorist models emerged because previous management theory was far too simplistic and did not address the needs of the individual. Maslow and McGregor tried to address individual needs and their relation to the needs of the organization (6, 7). This gives us some insights into group process and interpersonal relationships among the workers, and it focuses management on the needs of employees as people, not just as part of the production process. But there are also some limitations of this view. People are complex beings, and it is never easy to predict what anyone will want at any given moment. Managers themselves often find it easier to focus on processes than on people. Organizational goals and objectives are frequently stated in other than human relations terms. Nonetheless, these theories remain at the core of modern human resource management and are still robust today in their insights and perspectives.

Quantitative Theory

Quantitative theory emerged as the world moved out of World War II and industrial production shifted its focus from military hardware and support of national causes to consumer goods and services. Corporations moved from "cost is no object" to a cost-containment, profit-driven mindset. The legions of industrial engineers, previously focused on industrial efficiency to support the war effort, were now charged with improving corporate efficiency. The origin of the statement is unknown, but the adage "if it can be measured it can be managed" took hold, and strong quantitative approaches were adopted.

Management science focused very specifically on the development of mathematical models (reference 8, p. 49–52). Early computer applications in this direction centered on helping managers find the best way to do things and save money. Linear programming models and inventory management and control—difficult mathematical concepts, often beyond the ability of a person to compute within rational time limits—became trivial questions when the power of even the simplest of computers was employed. But this also looked very much like the pendulum was swinging back into Taylorism and the dehumanization of the organization. Much of senior management in the post-WWII period was made up of former officers and military veterans who placed their focus on the accomplishment of the task at hand, often at the expense of the welfare of their employees. Employee work groups could not readily convert to a mathematical problem; hence, a new concept of management needed to be developed to bring together the needs of the corporation and the needs of the individual.

Operations Management and the Integrated Theory

Operations management was the attempt to develop a set of tools, applied mathematics, and human resource management to develop techniques to produce products and services more efficiently (reference 8, p. 49–52). Operations management often includes substantial measurement and analysis of internal processes. Ultimately, the nature of how this is accomplished depends very much on the nature of products or services in the organization, for example, retail, manufacturing, or wholesale. As with management science, though, the focus moved away from the individual and related more to the organization at large and how it interacted within the larger business environment (9).

Management by objectives (MBO) tried to integrate the concept of managing what can be measured while simultaneously bringing the individual into focus (reference 10, p. 126–127). At its simplest, in MBO every employee has a set of objectives to achieve, which together with all other employees in the organization will pull the enterprise toward its overall objectives. All targets are quantifiable and easily recognizable for their value to the company. Realistically, though, performance management is difficult, and inevitably the biases and personal agenda of the rater may come into play. Key points here are that objectives must be clearly defined, plans for achieving the objective must be detailed and clear, and there must be ongoing monitoring to see if the plans are moving forward (reference 10, p. 126–127).

Thus, the quantitative perspective accelerates the development of mathematical techniques for decision making and the setting of objectives. This modeling methodology dramatically increased the awareness of organizational processes and assisted greatly in organizational planning. As with the previous theories, however, human behavior is unpredictable, and following the dictate "garbage in/garbage out," mathematical models based on faulty information or assumptions will not lead to better management.

With the failure of mathematical modeling to fully address management problems, integrated theory—a new, more holistic view of the organization—emerged (reference 8, p. 56–57). Speaking generally, the integrated systems approach to management tried to incorporate the best of all that came before it while trying to maintain a human focus (11). **Systems theory** represents the merger of many ideas from scientific management and the human relations movement. It is project based and strives toward organizational synergy. There are those who would nest systems theory under the heading of quantitative management. Such an approach misses the point that systems theory is all-encompassing, whereas the basics of quantitative management are pure mathematics.

A system, in this context, is defined as an organized unit composed of two or more interdependent parts, subsystems perhaps, where the whole can be identified as

something separate and apart from its surrounding environment (reference 8, p. 58). Consider an organization to be a system. It will experience problems, and issues will need to be addressed. The systems-oriented manager, rather than merely trying to manage the problem away, will look at the opportunities a problem might bring and will try to bring all available resources from his organization to bear on the situation.

Much of systems theory resembles the scientific method: you see a problem to be examined, you hypothesize a solution, you design a controlled experiment to test that hypothesis, you collect and analyze the data. The key here is to maintain your focus and attention on the entire organization (11). You cannot change one part of the system without affecting all the others. Systems theory might seem quite basic, yet it is extremely difficult to examine the whole of an entity. We are familiar with many approaches to break down problems into identifiable and workable parts. It should be noted that information system tools to allow a real-time focus on an entire organization have only recently become available.

Into this mix, and possibly in part because of the difficulty of trying to manage the whole, a **contingency theory** of management emerged. Contingency theory asserts that when managers make decisions, they must consider all aspects of the current situation and then act on only those aspects that are most crucial (12). You keep the entire entity in mind but only focus on that which seems most important. While you will be impacting the entire system, you must also keep your attention directed at that which seems most pressing at that moment. Thus, there is no one "best way" to manage an organization. The contingency perspective would say that universal theories do not apply to every organization, because every organization is unique. This falls under the subheading of an integrated theory, because it presupposes that the decision maker involved will keep in mind that even though his concern might be on a subsystem of the larger organization, it is still nested in that larger system.

As powerful as the above integrated approaches might be, they soon were dwarfed by the emergence of the various **total quality management** and **continuous quality improvement** models.

W. Edwards Deming is often referred to as the founder of the modern quality movement (reference 8, p. 622; https://deming.org). An American whose ideas were developed based on Western management theory, he gained wide prominence through the acceptance of his theories by the Japanese. The Japanese themselves will say that the application of his ideas led in great measure to their postwar economic success. Deming's theories by themselves are very basic and deceptively simple to implement. To start, he believed that **total quality management** (TQM) begins at the corporate level. The entire enterprise must have a deep and wide-ranging commitment to the continuing improvement of products and services (13). The enterprise must always move forward and keep innovating toward the next improvements. Quality needs to be a part of every stage of production, where there is continuous inspection and review. The quality check should not be saved until postproduction. True quality requires quality that can be measured and must be willing to pay the price for that result. Managers should not rely on low-cost bidding by suppliers just to save money while sacrificing quality. Finally, managers should initiate training programs and leadership models to help people do a better job and to empower them to speak out and respond when problems are detected (reference 14, p. 129). Deming says that if you do this you will produce a better product.

More than 40 years after their adoption, these concepts seem obvious and basic to modern industrial management. At the time, however, they were revolutionary, and their adoption by the Japanese changed the meaning of the phrase "made in Japan" from cheap and poorly made to solid and reliably built (reference 14, p. 98–99).

Total quality management (TQM), one of the first so-named theories of the quality movement, is a structured system for satisfying internal and external customers by integrating the business environment, continuous improvement, and technological and production breakthroughs (reference 15, p. 15–37). "Structured" means it is strategy driven by the identification of customer wants and needs that have been determined through ongoing interaction with those customers. TQM is a description of the culture, attitudes, and organization of a company that aims to provide, and to continue to provide, its customers with products and services that satisfy their identified needs. It is a corporate culture that requires quality in all aspects of the company's operation, with things done right the first time, while defects and waste are removed from operations. The products are designed to be quality output, and the manufacturing and product systems follow through to meet that goal.

There are differences in approach that are important to compare. As an example, Ford Motor Company strove to become the number one producer of automobiles by determining first what price the consumer would accept and then working toward making a car that could be produced for that price. The challenge was not quality. The challenge was production efficiency and unit cost (reference 8, p. 130–131). The production of Ford cars can be seen as a "Taylorism" experiment: divide the work into its smallest parts, make each part as efficiently as possible, and ramp up production to get quantity pricing. On the other hand, consider the production of a Toyota in 1975. Via marketing research, the focus was on what level of quality the customer expected for every unit of cost (13). Toyota's approach was to design the product to meet the quality demands of the customer. They focused on producing a

quality product at each step, not throughput. They acknowledged that the customer does not want the cheapest car, but rather the best value for the selling price. The attitude shift was from car production at whatever the market will bear, to getting the best-quality product onto the market as the best value to be found.

Many organizations have trouble integrating a TQM model into their operations. Fewer than half of those who have adopted a TQM approach report any improvement in quality, productivity, competitiveness, or financial return (reference 15, p. 6). But that percentage may be deceiving. The focus should be on successful operations, where many more than 50% rely upon TQM to maintain their success.

A subset of the TQM movement is often referred to as **continuous quality improvement** (CQI). What separates CQI from TQM is the focus on the employee (16). A CQI approach forces the organization to look at its employees and their work as part of a continuous process. CQI is thought to have a more human face than TQM; this distinction is not always clear.

Whatever acronym you choose to use, the quality management approach to production changed the way manufacturers looked at their world. The focus on cost reduction and profit improvement has been replaced forever by a focus on the customer and the production of a quality product that meets the customer's needs at a reasonable price.

Management theory and thought continue to move forward, with ongoing work in the behavioral and individual employee world, as well as focusing on the organization and production processes.

Above, it was noted that management by objectives was one of the most widespread approaches to working with individual employees. Taking a step farther, the approach has led to the popularity of interest in lifelong learning, also known as **continuous lifelong learning** (reference 17, p. 332–336). The continuous lifelong learning process starts by identifying where a person is at that moment and where they would like to be in the future in their career. Assessment of the individual is an essential part of this self-identification, so that person can move to the next phase of the process. The next phase of the process has individuals taking initiative, to strive to achieve their goals.

There are several key factors for this process to be successful:

1. First, the employer recognizes that crucial to lifelong learning is the concept that no one individual will necessarily stay in that job or with that employer forever. As people learn and grow, they move on to new jobs and experiences.
2. Second, individuals can take charge of their lives to reach their full potential. Self-empowerment is both a result and an employee need.
3. Third, everyone is accountable for and responsible for his or her individual progress. Some people might choose a mentor for assistance, but the mentor is not responsible for the individual's growth.

The connection to the employer and management is that learning-inspired/driven employees do better work and absorb the total quality management message much more effectively (reference 17, p. 332–336). TQM and CQI require employees to think and to consider the options available to them to work better and more efficiently. Dialogue between management and worker is enhanced when employees think in terms of their jobs as part of a lifelong journey, and they are learning and working toward better lives. This is almost a utopian vision but nonetheless is the direction in which much of the industrial world is heading.

Similarly, while on an individual basis the organization actively develops its employees to evolve and grow, on a product and process basis modern corporations are starting to work toward a **total product life cycle management** concept. This theory suggests that more than merely focusing on a product as a unit at a point in time, the organization needs to consider whether that product is in the ascendancy or is fading and adjust the product to their customer needs accordingly (18, 19). The marketplace is always moving forward, and the organization must move forward with it. Product design and production must think through the issues of product introduction and placement in the marketplace, ultimately the disposal and replacement of that product, and planning for the next generation of product to meet the customer's demands and needs. Similar in many ways to TQM, in which a product design defines its quality and use, the life cycle management theory goes a step farther to plan for product demise and redefinition as customers change their focus to something new. At some point the organization will decide to stop making or doing one thing and to move on to another. Life cycle management forces an enterprise, early in a product's life, to plan for its replacement (18). Thus, engineering is always thinking ahead, and employee education always works toward preparing the workforce for the future.

Similarly, **process reengineering** forces the organization to rethink how it does its work and how it can be done better (reference 20, p. 103–129). Again, this is an extrapolation on TQM and CQI. The difference is that with TQM and CQI you are always trying to improve what you already do. Process reengineering suggests that you entirely abandon what you are doing now in favor of something entirely new and different (reference 20, p. 174–192). In the extreme, process reengineering assumes the current process to be irrelevant. Thus, start over with a clean slate and see what you can do. Those subscribing to this theory think in terms of vision and the future (21). What must we

look like at some future point to meet the needs of our customers? What technological changes have taken place that we should incorporate to make us better and more responsive? What will our customers expect of us in the future that we must plan and build toward now?

A reengineering tenet is that technological change has negated all that we do now. Thus, this is not merely a desire on our part to change what we do to improve ourselves. As technology advances, it then moves forward to invalidate what is currently the "best." As a result, in order to implement the newest technologies, rebuilding occurs starting from the beginning. Competition in the marketplace demonstrates that new organizations that do not use outdated methods are likely to surpass you. Thus, finding new ways to do things, redesigning processes around new technology, is central to organizational survival.

Finally, many believe that the customer base we work with now is much more quality sensitive and driven, with only the best surviving. Defining what is the best is always a challenge, with **Six Sigma** as one approach. A thorough coverage of Six Sigma can be found at the Six Sigma website, which covers in depth all aspects of Six Sigma. That site defines Six Sigma as a highly disciplined process to focus on developing and delivering near-perfect products and services (http://www.isixsigma.com/new-to-six-sigma/; accessed July 2022). "Sigma" is a statistical term that measures how far a given process deviates from perfection. Knowing that deviation, one can predict how many errors and defects there will be in a process; thus, one can systematically try to find and remove them.

The Six Sigma website states the following: "Six-Sigma by definition is not more than 3.4 defects per million events." A Six Sigma defect is further defined as anything outside of customer specifications (reference 22, p. 184–202). Thus, it is not merely an operational or production defect. A process can function perfectly, but if the end result is outside of what the customer wants, it is a product defect.

Six Sigma incorporates product and process improvement. It integrates many of the features of TQM and CQI and process reengineering. Those who apply the theory refer to two acronyms: DMAIC (define, measure, analyze, improve, control) and DMADV (define, measure, analyze, design, verify) (reference 22, p. 329). Six Sigma process implementation staff are often referred to as Green Belts and Black Belts, suggesting a special trained status and the aggressive nature by which the measurement and improvement processes are implemented (reference 22, p. 125–145).

Six Sigma is another in the many process and product review methodologies, all with the aim of giving the customers what they want. Six Sigma has "raised the bar" on the definition of product and process quality. Like all management techniques, commitment at all levels of the organization is required, and this becomes the primary message carried in all of the above-described modern and new theories.

Table 1.1 Emergence of management theories

Emergence	Theory
1940s	Operations management
1950s	Systems theory
	Management by objectives
	Total quality management
	Continuous quality improvement
1980s	Six Sigma
	Lean
1990s	Process reengineering
2000s	Lean Six Sigma

Lean Six Sigma adds additional layers by including a measure of time efficiency to the already established efficient production process. As stated on the Six Sigma website, "Lean production is aimed at the elimination of waste in every area of production including customer relations, product design, supplier networks and factory management. Its goal is to incorporate less human effort, less inventory, less time to develop products, and less space to become highly responsive to customer demand while producing top quality products in the most efficient and economical manner possible" (http://www.isixsigma.com/new-lean-six-sigma/; accessed July 2022). For more information on quality management, see chapter 18 of this volume, "Quality Management." Table 1.1 summarizes the emergence of various management theories over the past 80 years.

Decision Making and Problem Solving

Decision making is the process of making choices by identifying a decision, gathering information, and assessing alternative resolutions. Decision making is an integral part of modern management, with rational or sound decision making a primary function of management. A decision can be defined as a course of action purposely chosen from a set of alternatives to achieve organizational or managerial objectives or goals. Most everyone makes many decisions every day. Granted, many decisions are small and made almost unconsciously, while other decisions are more significant, requiring a more conscious effort, time to study, and consideration of the potential consequences. Regardless of the nature of the decision, every decision encompasses elements of a basic decision-making process (23).

Decision making by leaders and managers exhibits significant differences (see Table 1.2). Including staff in collecting data, analyzing data, and decision making, though, can also affect efficiency and effectiveness in an organization.

Table 1.2 Decision-making differences between leaders and managers[a]

Characteristic	Leader	Manager
Vision	Search for long-term opportunities	Maximize current opportunities
Communication	Tell people why we are doing something	Tell people what to do; listen to have an effect; listen for understanding
Question(s) asked:	Why?	How? What?
Planning	An opportunity to excite, educate, prepare for future	A path to follow
Power	Something to share and use for the goal of the group	Something to have and use
Approach to problem solving	Something to learn from, opportunity for growth	Something to solve, to fix
Perceived role	Integrator; maker of decision makers	Controller or decision maker

[a] Adapted from reference 34.

A common rule of thumb is that decisions should be made at the lowest possible level in an organization. The closer one is to the information and effects of a decision, the higher the quality of that decision, so the manager is not always the best person to make the final decision (23).

Decision making is the complex process of choosing one alternative from among a set of alternatives. Inherent in this definition is an awareness that a decision needs to be made, that alternatives need to be developed and considered, and that one "best" alternative is chosen and implemented.

What Is Decision Making?

The science of decision making, as described in the literature, applies models based on deductive, inductive, analytical, and simulation approaches. These models describe decision making as a deliberate process, differentiating managerial decisions from habit and reflex. Decision making also has an artistic side, drawing on the decision maker's creativity and judgment. In addition, managers often base their decisions on personal or organizational value systems and philosophies.

Since the closer one is to the information and effects of a decision, the higher the quality of the decision, the greater is the empowerment of individuals in an organization. This makes them better able to participate in decision making, which is an essential skill. Pickett notes that empowerment requires "stretching, coaching, training, giving authority, and implying permission to make mistakes (obviously, this must be judiciously applied)" (24). When people in an organization are empowered decision makers, they think differently, act differently, and are more energetic. Table 1.3 outlines multiple concerns in decision making.

Table 1.3 Concerns in decision making

Parameter	Rules	Question(s)
Quality	1. Leader information rule	Does the problem possess a quality requirement?
		Do I have sufficient information to make a high-quality decision?
	2. Unstructured problem rule	Is the problem structured?
Acceptance	3. Acceptance rule	Is acceptance of the decision by subordinates important for effective implementation?
	4. Acceptance priority rule	If I were to make the decision by myself, am I reasonably certain that it would be accepted by my subordinates?
Quality and acceptance	5. Goal congruence rule	Do subordinates share the organizational goals to be attained in solving the problem?
	6. Conflict rule	Is conflict among subordinates likely in a preferred solution?
	7. Fairness rule	

[a] See reference 28.

Types of Decisions

There are various types of decisions. Decisions can be studied and classified from various perspectives (25). Some decisions are strategic or tactical, with the former focusing on the means to reach a goal, and the latter focusing on steps or objectives to be accomplished. Some decisions are administrative, requiring substantial resource commitment; other decisions are operational, dealing with day-to-day activities. Some decisions are programmed because they are routine and repetitive in nature. Other decisions are termed nonprogrammed because they are novel and unstructured. Still other decisions are individual or group, differentiated by who makes the decision (26).

Strategic decisions are concerned with an organization's relationships with the external environment, the choice of a competitive posture, and the formulation of major policies. The goal is to arrive at the best plan for the organization, given operational, economic, logistical, and political constraints. Examples include mergers, expansions into new markets, and off-site testing facilities.

Tactical decisions are, as the name implies, tactics or steps for implementing the organizational strategy. These can be categorized further as administrative decisions or operational decisions. Administrative decisions deal with authority, responsibility, and accountability relationships. Operational decisions handle the routine, day-to-day problems in accomplishing work.

Decisions may also be classified as programmed or nonprogrammed. **Programmed decisions** are structured and recur with some frequency (25). For example, the decision to reorder supplies and reagents for the laboratory is a programmed decision. Structure exists in terms of

quantity to order, purchase requisition process, etc. This decision is made on a recurring basis. Programmed decisions are guided by rules, policies, and procedures.

By contrast, **nonprogrammed decisions** are relatively unstructured, in part because they occur infrequently (25). Situations that have never arisen exactly like the present or are very complex usually do not have procedures to guide the decision-making process. Some years ago, when the concept of core laboratories was introduced, the decisions necessary to plan these high-volume, cross-specialty facilities were unstructured, hence nonprogrammed. A decision today to purchase experimental equipment is a nonprogrammed decision. Nonprogrammed decisions require intuition, creativity, and a tolerance for ambiguity.

A manager's natural tendency toward decision making prompts two more decision types: **intuitive decisions** and **judgmental decisions**. Intuitive decisions are made using hunches, subjective values, and personal or emotional factors. A manager who becomes impatient with the time it takes to gather information and sort through details may make an intuitive decision. The manager's decision cannot be readily explained by looking for details but is more likely rationalized by a perception of the "big picture," a holistic view of the situation. Individuals who tend to make intuitive decisions believe creativity comes from inspiration rather than perspiration.

Because of the education and experience in clinical laboratory science, most laboratory managers tend to make **judgmental decisions**. These decisions are reached after data are gathered, facts analyzed, and concrete examples explored. Judgmental decisions rely on objective analysis and rational procedures. For those decision makers who tend to make judgmental decisions predominantly, creativity is very challenging. The potential danger of "analysis paralysis" is a real threat (25).

Individual versus Group Decision Making

Individual versus group decision making needs to be strongly considered. The involvement of groups in decision making adds both benefits and liabilities. Groups tend to make more accurate decisions compared to individual decisions, although reaching a group decision is slower. Social interaction in group decision making tends to foster competition among members for respect, provide social support, and self-correct errors that might occur when an individual is making the decision alone. Group decision-making dynamics sometimes are counterproductive, however. When not constrained by a mandate to reach a group decision, individuals tend to produce more ideas, more unique ideas, and better ideas. Generally, people accept better decisions reached by a group versus an individual if they feel their participation in the decision was considered and valued. Obviously, acceptance of a decision is key to commitment and implementation.

Vroom and Jago (27) have shared their insight into the question of whether a decision should be made by the individual manager or with involvement of the affected group of employees. Originally researched by Vroom and Yetton, these insights consider three criteria: (i) quality or rationality of the decision, (ii) acceptance or commitment of subordinates to implement the decision, and (iii) time required to decide.

The Problem-Solving/Decision-Making Process

While it is true that decisions are choices, decision making and problem solving is a process of steps. Many decisions can be made quickly with little attention to the steps along the process. The more complex the problem, and the more mission-critical the objectives, the more important each step is to reach a successful, high-quality decision. The problem-solving/decision-making process described below and illustrated in Fig. 1.1 is a continuous circle of events (23). The steps overlap in practice, and the connection of all steps leading back to solving the identified problem or meeting the intended objectives is important to "closing the loop."

Step 1: Identify the problem or determine the objectives. Identifying the problem requires a manager to first diagnose the situation. Too often a symptom of the problem is misidentified as the root cause. For example, a manager who identifies poor morale in the laboratory has misdiagnosed the situation. Poor morale is a symptom of an underlying problem. The range of root causes could be low pay, unappreciative supervisors, or lack of respect from coworkers, among other causes. Failure to define the problem in step 1 will negate all subsequent steps to solve the problem. Similarly, clear definition of objectives for a decision provides a constant point of reference when subsequently gathering information and developing alternatives.

Step 2: Gather facts and evaluate information. At this step, the manager will learn whether he is dealing with a programmed or nonprogrammed decision. Are there rules, policies, and procedures that need to be followed? Has someone already solved this problem, and if so, how similar are those characteristics to this situation? Is there a need to get group input, and if so, individually or collectively, and from whom? Figure 1.1 shows the influence of the manager's perceptions of information gathered as data are evaluated. The natural tendencies to either rely on the five senses to identify factual details (sensing) or to use hunches and a more holistic view (intuition) will be part of this step.

Step 3: Develop and evaluate alternative solutions and options. Some possible solutions will be obvious; other solutions will be more creative. The tendency to

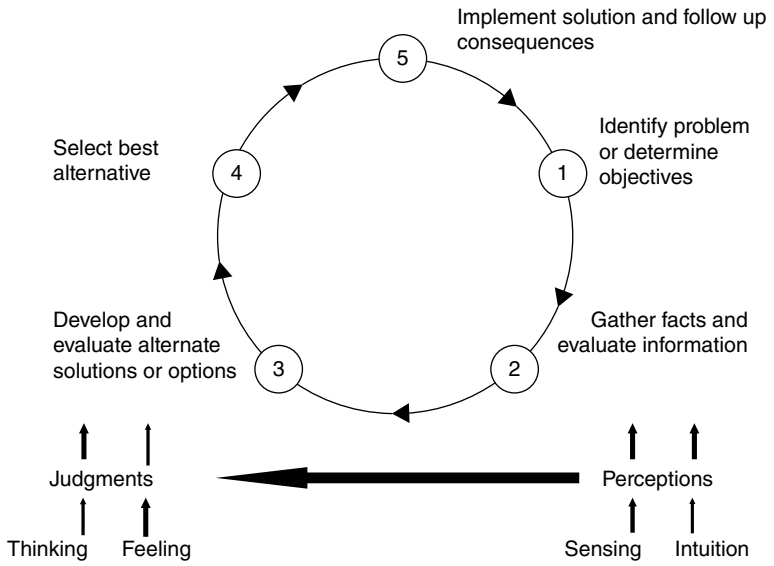


Figure 1.1 Problem-solving/decision-making process.

quickly adopt the first viable solution may be time-efficient but lead to a lower-quality decision or solution. In general, the more important the decision, the more alternatives should be developed. At this step, as shown in Fig. 1.1, the evaluation of options will be influenced by the judgments of the decision maker. The use of both subjective values and objective analysis will lead to a better sorting of potential options.

Step 4: Select the best alternative. After considering each option in light of the situation or objectives to be achieved, the manager chooses the one most likely to be the highest quality with the greatest acceptance within the time available for decision making.

Step 5: Implement solution and follow up consequences. The chosen alternative is implemented, and over time the manager determines whether the problem has been solved or the objectives met. The potential pitfall here is to ensure that once the chosen alternative is implemented, the process is complete. Two key questions need to be answered: (i) Did the chosen alternative work? and (ii) Are there unintended consequences to the decision that now must be addressed?

All decisions involve some element of risk. Risk is based on uncertainty. The greater the outcome uncertainty of the alternative chosen, the greater the risk. A manager's decisions can be influenced significantly by both his own and his organization's propensity for risk. A manager with a high propensity for taking risks with decisions, in an organizational culture with a low propensity for risk, will likely experience problems. Good decision making relies on knowledge of both the importance and components of the process. It requires an awareness of personal skills to determine the best way to reach the highest-quality decision with the greatest acceptance in the amount of time available. Good decision making requires experience and learning from one's mistakes (reference 17, p. 66–68). Good decision making requires the ability to reflect on information, then decide (28, 29). Table 1.1 summarizes the emergence of various management theories over the past 80 years.

Management Functions

The study of management is typically broken out into four primary areas: planning, organizing, directing, and controlling. This section provides an overview of those management functions, presented in basic, practical language.

Planning

Planning is the process of formulating objectives and determining the steps which will be employed in obtaining them. No modern healthcare organization can be effective without an overall plan of action (reference 18, p. 30). **Strategic planning** is a methodical process whereby an organization defines its mission, identifies directions, develops a unified approach, prioritizes long- and short-term goals, assigns accountabilities, and allocates financial resources. If done properly, strategic planning involves supervisors and staff, and it requires the use of time and resources. Therefore, a manager must plan to plan. Before any planning is initiated, a number of important questions must be answered, including the readiness of the organization to engage in such a process, whether the culture of the organization generally supports a planning process, how committed the organization is to a time- and energy-consuming process, who

should be involved in the planning group, how and when the process should be initiated, how others in the organization who are not directly involved in the planning process will be informed about the process, and the time frames for the process (reference 30, p. 6).

The objective of planning is to set an achievable course of action by establishing long- and short-term goals, monitoring progress, and establishing an environment where day-to-day activities are well controlled, measurable, and thoroughly understood. The plan helps the organization develop an action-oriented approach and identify the pieces needed to build a successful operation. Good strategic planning is a structured process. "Structured" means that the plans of individual laboratory sections must fit into an overall plan that covers the entire laboratory operation. It is a "process," because good plans are not produced in isolation according to some predefined formula.

Strategic planning presents challenges. The more far-reaching the laboratory's mission is defined, the greater the challenge. One constant, whenever the paramount resource of an organization is the experience of its people, is the absolute necessity to include the input of the staff (17). Points to be considered when planning include:

- Involve staff at every level in developing a strategic plan. Solicit feedback from individuals who really know what's going on and who will be responsible for executing the plan. You will get great ideas and critical buy-in by getting staff at the bench level to offer input during the process.
- Be flexible in developing a plan by circulating drafts and allowing people to provide feedback.
- Ensure that everyone knows their responsibility for deployment of the plan and that feedback mechanisms are implemented. The most carefully written plan will fail if those responsible for its execution do not know their roles, deadlines, and resource allocations. A defined feedback mechanism will ensure that the plan does not get lost in daily crises.

An important tool of planning is assessing the laboratory's strengths, weaknesses, opportunities, and threats, through what is called a **SWOT analysis**. A SWOT analysis is a tool that can help to analyze what your company does best right now, and to devise a successful strategy for the future.

If one does not already exist, at the beginning of the planning process a **vision statement** should be written to articulate what the organization seeks to become. A vision statement is an internal document, by design. It is intended to inspire those within the organization to maximize their potential, and by so doing, to maximize the potential of the organization. A vision statement need not be wordy; some of the best vision statements are brief and succinct. A vision statement should be lofty in its ideals. It should state a common purpose, and it should express the long-term goal of the organization. An example of a vision statement, from the Virginia Commonwealth University (VCU) Department of Pathology, states, "Our vision is to become a preeminent Department of Pathology in the United States, which is recognized for excellence in biomedical research, the education of health care professionals, and the innovative application of science and technology to the diagnosis and management of human disease" (https://pathology.vcu.edu/about-us/, accessed 12 September 2023).

A **mission statement** for the laboratory should also be developed at the beginning of the planning process. A mission statement answers certain fundamental questions about the organization, such as What is our purpose? In what activities will we be engaged to accomplish that purpose? and What are our basic values and shared beliefs? Having a clearly articulated mission statement benefits the planning process by defining the organization's purpose, but it also benefits the organization by reminding everyone, staff and clients alike, about the organization's purpose. An example of a mission statement, also from the VCU Department of Pathology, states, "Our Mission is to provide high quality, cost effective molecular pathology services in a manner that supports the patient care, education, and research missions of the Virginia Commonwealth University Health System and School of Medicine" (https://pathology.vcu.edu/about-us/). Note that this statement clearly defines what the organization is and the clientele that it serves. As planning progresses, people should look to the mission statement for guiding principles in the decision-making process.

The mission statement should be credible and closely aligned with the organization's actual purpose. Credibility is lost when the mission goes beyond the stakeholders' ability to believe in it (reference 30, p. 67).

Planning is done to produce a list of goals and strategies that will guide laboratory management decisions for a period of time. Through discussion, the planning group produces a written document that lists specific goals and strategies. A goal is an end or an outcome that one hopes to attain. An example of a goal is "to enhance laboratory revenue by increasing referral testing from external sources." This is a clear statement of something that the laboratory will try to achieve.

Once goals and strategies are established, they must be prioritized between "must do" and "want to do" decisions. Action items are assigned to specific people to be responsible for delivering results. Attach specific names to specific action items, because if everybody is accountable for a certain task, then they will take proprietary ownership to make certain that the task is done correctly and in a timely way.

Finally, a reporting mechanism must be established to review progress, reevaluate priorities, and make updates based on a constantly changing operating environment. The ideal venue for reviewing metrics is a regularly scheduled meeting attended by everyone who has assigned

accountabilities. At this meeting, accountable people are asked to report upon the progress made on their assignments. A regular reporting forum helps to maintain momentum by removing the human inclination to procrastinate. Monthly, or perhaps even weekly, meetings should be scheduled to discuss progress toward stated goals and objectives.

A strategic planning process includes the following steps (see Appendix 1.2):

1. Select a knowledgeable planning group.
2. Perform an environmental analysis.
3. Identify strengths, weaknesses, opportunities, and threats (SWOTs).
4. Make a manageable and realistically achievable list of goals.
5. Prioritize goals.
6. Develop strategies to accomplish goals.
7. Assign accountabilities and timelines.
8. Measure progress with metrics.
9. Review progress and make updates on a regular basis.

For more information on strategic planning, see chapter 28 of this volume, "Strategic Planning."

Organizing

Organizing is the process of structuring activities, materials, and personnel for accomplishing predetermined objectives (reference 18, p. 136).

One of the most important functions of a manager is to organize the activities of the laboratory in such a way that use of time is carefully considered, so that effort is minimized while output is maximized. Profitability, efficiency, and quality are often determined by how well resources and workflows are organized.

An essential management tool is the **organizational chart** (see Appendix 1.3). An organizational chart shows hierarchical relationships between functional areas. It is a visual depiction of the organization, which helps to clarify workflow, reporting lines, and areas of responsibility by explicitly listing delineated work areas, be it by division, laboratory, or medical specialty.

To be well organized is to develop a structured approach to time management. A time management system allows a manager to:

- Minimize time wasted on nonproductive issues
- Be prepared for meetings
- Be aware of existing commitments
- Understand the capacity to take on new assignments and when to say "no"
- Plan each day's work efficiently and effectively
- Make certain that no project (large or small) is neglected

Simply stated, the conscious use of a time management system allows a manager to be well organized and well prepared. Failure to use a system ensures disorganization and lack of preparedness.

An effective organization has policies and procedures. **Policies** express behavioral expectations within the workplace. All policies have seven basic characteristics: they must be (i) well thought out; (ii) flexible enough to be applied to both normal and unusual situations; (iii) acceptable to those who apply them; (iv) consistent; (v) objective; (vi) clear and communicated to those individuals to whom they apply; and (vii) continuously reevaluated and changed when necessary (28). **Procedures** are formal steps to guide an employee through a specific job task. A procedure is a written, sequential course of action to be taken to achieve a desired outcome. A laboratory manager must maintain current, concise procedure manuals for all processes that are performed in the laboratory. As with policies, the book of laboratory procedures should be continuously reviewed and revised by a team of experts to ensure that they are up to date and in compliance with the most current regulations and standards of care. Accreditation of the laboratory will be judged in part on the accuracy and thoroughness of the procedures, so maintaining them should be among the highest priorities of all laboratory managers.

A laboratory manager must be a master of all the interconnected processes within the laboratory. These processes are logically sequential, and they are accomplished in such a way that one process or step must be completed before the next can begin. This is known as **workflow,** or organizing tasks in a way to accomplish a specified result. An important tool for analyzing workflow is the **flowchart.** Process design flowcharting is a fact-gathering technique used to make the effort of a task visible by writing down what is done. A flowchart graphically illustrates the relationships between necessary tasks.

Clinical laboratories have unique staffing needs. Each laboratory has an ideal number of employees based upon throughput and automation. A manager must ensure that efficient staffing is always maintained. Accurate staffing must align to the organizational chart, taking into consideration how each laboratory component serves the ultimate mission of the laboratory. Staffing should be a topic of discussion in the strategic planning process. A well-thought-out strategic plan considers staffing, enabling a manager to make long-term predictions about future staffing needs.

Directing

Managers direct people and activities. Staff members require and expect direction in their activities. Directing is the process of influencing people to attain predetermined objectives (reference 18, p. 30).

Communication is among the most important components of directing/management. Clear written and verbal communication—from manager to employee, from employee to manager, between managers, and between peers—influences action. Without it, there is no effective way of articulating expectations, expressing concerns, providing feedback, and ensuring that policies are implemented. Communication must flow in all directions. It must be concise, clear, consistent, and continuous. Employees rely upon regular feedback from their supervisors. Supervisors rely upon their employees to inform them of their needs. People at all levels of authority within the laboratory rely upon communication with their peers to remain aware of changes in policy.

In every organization, there are four basic communication flows through which messages can be passed: **downward, upward, lateral,** and **diagonal.** Downward communications travel from the superior to the immediate subordinate. Downward communications are used to transmit information and instruct employees in the performance of their jobs. Upward communication travels from the subordinate to the immediate supervisor, and it is used to provide feedback on how things are going. Lateral communication takes place between people on the same level of authority within an organization, and it is used for promoting coordination and teamwork. Diagonal communication occurs between people who are neither in the same department nor on the same level of authority within the organization. Diagonal communication is used for cutting across organizational boundaries to save time (reference 18, p. 211–214).

The basic attributes of good-quality communication are attention, acceptance, and empathy. **Attention** is the thoughtful consideration of others. When speaking to someone, be considerate of his or her concerns, needs, and experiences. It requires active listening to what people are saying. Ask questions to clarify concerns. Affirm your understanding by paraphrasing and restating their concerns until there is no ambiguity and no room for misunderstanding. Active listening should always be incorporated when communicating with staff members.

Acceptance is the act of favorably receiving someone's thoughts and opinions. This does not necessarily imply agreement but conveys that you understand the concerns being expressed and that you will keep an open mind. Successful listening is an active, dynamic process. Alertness at every point of the communication encounter is a prerequisite for the supervisor, as well as for the subordinate (reference 31, p. 86).

Empathy is a very important aspect of communication. It is the ability to share in another's emotions or feelings. It is the identification of another's thoughts and attitudes as they might apply to a situation. When placed in identical circumstances, every person has his or her own interpretation based on personal experience and bias. Therefore, to truly connect with an employee, one must make every effort to understand his or her perspective in each situation (reference 31, p. 87).

Finally, it may seem obvious, but it bears mentioning that a manager must establish trust and maintain credibility with the staff. Trust is earned through honest communication and consistent follow-through on promises made. Trust is the foundation of good working relationships. Credibility cuts both ways in the manager-employee dynamic. Each party must take responsibility in establishing trust and maintaining credibility.

Controlling

Controlling is the process of determining that everything is going according to plan (reference 18, p. 30). Every employee should have a **job description,** which is a written agreement concerning the responsibilities of the position. The job description should include a job title, a compensation classification or range, the name of the supervisor who will review performance, a specific and detailed listing of responsibilities, and a performance evaluation schedule. Then a regularly scheduled, structured evaluation is a necessary expectation of employees. People deserve to know how they're doing in relation to a written set of expectations about performance. Regardless of the purpose or format of an appraisal, there are a few critical elements that must be included: standards and criteria of performance, communication of these standards and criteria to the subordinate, adequate frequency of appraisal, and a clear communication of appraisal results.

A **performance appraisal** provides an employee with valuable written feedback about progress made toward specific employment objectives. It serves the employee's need for objective evaluation about how he or she is doing. It also serves the manager's obligation to assess performance and provide constructive feedback. It is the manager's opportunity to put into writing an employee's level of competence measured against the stated requirements of the position. An appraisal also provides a forum for discussion about the employee's training needs, salary expectations, professional development, and career progress. A properly conducted performance appraisal is a two-way conversation, with the manager actively listening to the employee's feedback.

Summary

A laboratory manager has unique skills and a high level of daily responsibility spanning all areas of the organization. Because the technical aspects of running a laboratory are tightly regulated, when technical problems arise there is very often a written set of guidelines that dictate a solution. However, when it comes to managing the human side of the laboratory, there are daily challenges for which there

are no rulebooks and no obvious solutions. But there is a set of time-tested management tools for use by laboratory managers to address these daily challenges. A laboratory manager must become familiar with these tools and use them daily to gain confidence and experience in managing the human side of the laboratory.

The Evolving Models of Clinical Laboratories

In recent years the trend in healthcare delivery has been movement away from separate, independent healthcare entities to larger organizations through the process of consolidation. As part of this trend, many believe the clinical laboratory landscape will similarily evolve, with movement towards large regional laboratory networks that will be formed as a result of laboratory consolidation. The number of laboratories will reduce, driven by outsourcing of laboratory services, competition between laboratories for hospital work, and the commoditization of laboratory tests. Laboratory staff will be expected to deal with demand management and will be responsible for providing additional consultative services related to laboratory testing. The future role of laboratories will be more geared toward quality control, reducing laboratory errors, and eliminating unnecessary testing. Laboratory staffing shortages will continue to be a source of concern, leading to further automation of laboratory services. Also, the future of laboratory medicine will be towards more point-of-care testing. It will involve the integration of point-of-care testing into patient management strategies and pathways of care and more testing at home.

Centralized Testing

Laboratory testing is performed in many different settings, ranging from large, centralized reference labs such as Quest and LabCorp, which perform many complex tests, to one's own home, where one might take a pregnancy test or monitor blood glucose levels. All labs are not the same for the simple reason that not all tests are the same. Just as tests vary, labs also vary in complexity, the volume of tests performed, the technology utilized, and the number and type of professionals who perform the testing. Testing is performed in hospital laboratories, independent reference laboratories, or public health laboratories, at the point of care, or by direct-access testing or home testing.

All hospitals have a laboratory, which is usually proportionate in size to the population it serves. Busy hospitals may process hundreds of samples in just one shift. Tests that are performed include those needed in emergency situations, such as markers for heart attack like troponin, tests where results are needed rapidly for patient care like STAT testing, and other tests done in high volume, such as electrolytes. Hospital laboratories are generally used by all of the hospital's inpatients and outpatients, as well as outpatients who are being seen by hospital-affiliated physicians, such as at hospital-affiliated clinics and physician offices.

Independent reference labs are usually private, commercial facilities that do high-volume routine and specialty testing. Most of the tests performed are referred from physician's offices, hospitals, and other healthcare facilities like nursing homes. While most hospitals try to do as many tests as possible in-house, reference labs are used for specialized tests that are ordered only occasionally or that require specialized equipment.

Public health laboratories are run by state and local health departments to diagnose disease and protect the public from health threats, such as outbreaks of infectious diseases and environmental hazards. These laboratories perform tests to monitor, for example, the prevalence of certain diseases in the community, such as sexually transmitted diseases (STDs); to investigate outbreaks of foodborne illness or water pollution; and to screen newborns for various genetic and metabolic conditions at birth. They also perform rare or unusual testing that clinical laboratories do not offer, like specialized molecular tests to characterize a unique strain of *Escherichia coli* causing infection.

Laboratory tests may also be performed at the point of care—wherever a patient is receiving medical care, rather than in a laboratory. While results from clinical laboratories remain a crucial component of healthcare, they are now complemented by tests performed outside of the laboratory. Point-of-care tests (POCTs) span many areas of medicine and are performed in a wide variety of locations: in the home, at a doctor's office, in the emergency department, and increasingly on hospital units. Technology has caught up to the demand for convenient, rapid test results by enabling testing devices that are smaller, more portable, and easy to operate. Examples of POCTs are blood glucose monitoring, pregnancy tests, and hemoglobin, fecal occult blood, and rapid strep testing, to name a few. Tests included in POC programs must comply with quality standards comparable to tests performed in central laboratories. Point-of-care testing will continue to grow as new devices become available, in part because they provide immediate information to patients and their healthcare providers, allowing for more timely medical treatment.

Decentralized Testing

Direct-access testing (DAT) and home testing allow consumers to order their own laboratory tests without consultation with their healthcare practitioner. As with POCT, DAT has been growing over the past several years. DAT reflects a focus on health and preventive medicine, offering individuals the opportunity to take more active roles in their healthcare. Most states in the U.S. permit some degree of DAT. Over-the-counter home tests are an example of DAT since they do not require a prescription and can be bought and used at the consumer's discretion. It has

expanded to include laboratories offering clinical tests at the individual's request, without consultation with their healthcare provider. In some retail centers, people can walk into a laboratory and request certain tests; wellness centers offer health screens and other laboratory tests; and free-standing and mobile testing facilities such as those in grocery stores and pharmacies offer screening tests to the public. Most DATs limit the availability of tests to simple, general health tests such as cholesterol levels, urine cultures, diabetes screening, and pregnancy tests; however, increasingly sophisticated genetic testing is now offered using self-collection and mail-in of appropriate samples. As with POCT and home testing, DAT may benefit individuals by reducing the expense of office visits, providing vital information to individuals who are concerned with a health problem or who may otherwise avoid testing due to inconvenience or concerns over privacy. However, most insurance companies do not cover tests that are not ordered by a healthcare practitioner, so consumers should expect to pay out of pocket for these services. Laboratories providing DAT services must provide consumers with reference ranges and some assistance in interpreting the results.

The Basics of Financial Management

Departments and functional work areas can be grouped into two groups: revenue centers and cost centers. Revenue departments receive revenue for the organization for services rendered. A **revenue center** is an area of the organization which is responsible for generating a portion of the total revenues expected by the organization. Costs are expenditures incurred by the organization in the course of providing a service. A **cost center** is a unit within the organization whose primary purpose is to provide a service at the lowest possible cost. Examples of cost centers in the hospital setting include the departments of maintenance, dietary service, and medical records. The laboratory may be viewed as either a revenue center or a cost center, depending on how the organization is structured. In smaller institutions, the laboratory may be categorized as a single cost center, whereas in larger organizations, individual sections such as hematology and cytology are assigned as separate cost centers. However, the laboratory does produce revenue in the form of the billable test. In this case, the laboratory (or sections of the laboratory) could be thought of as a revenue center. There are other such departments in the hospital such as radiology and pharmacy.

Costs

Costs are expenditures and are classified as either **direct** (variable) or **indirect** (fixed). Direct costs are those that are specifically associated with a service or process. In the laboratory setting, examples of direct costs include instruments, reagents, and technical personnel. Indirect costs cannot be specifically associated with a certain service or process and must be paid even when a service is discontinued. Examples of indirect costs include clerical staff, inspection costs, and hospital overhead. These costs are shared among several departments or units and thus are allocated accordingly. An example could be hospital utility costs, which may be allocated as indirect costs to departments based on the square footage of the unit.

Direct costs change proportionately with a given change in volume. If the workload for a test or service increases by 10%, the direct costs of performing this test would be expected to increase proportionally. Indirect costs, on the other hand, do not vary as volume changes. As the workload for the test increased by 10%, the cost of the department manager's salary would remain constant.

There are costs having elements of both fixed and variable costs. They vary with volume, but not in direct proportion. These costs are called semivariable. Testing volume could continue to increase without additional supervisory staff, but there could be a breaking point where the test volume increase would necessitate another supervisory position, which forces an increase in the semivariable cost.

Revenue

Hospital laboratory revenues have continued to be reduced over the past few decades. Traditionally, laboratory revenue is paid as percent of charge (gross versus net revenue) or from a prospective payment system that reimburses hospitals based on diagnosis-related groups (DRGs) for hospital inpatient services (Medicare Part A). There is also an ambulatory payment classification (APC) (https://www.acep.org/administration/reimbursement/reimbursement-faqs/apc-ambulatory-payment-classifications-faq, accessed 12 September 2023) (31). Both the DRG and APC systems have shifted the financial risk from the payor to the provider. Another payment method involves laboratories accepting capitated payments based on an insurance carrier's membership, a per-member-per-month fee (PMPM). Laboratories agree to perform all required tests for an entire panel of patients for a monthly fee for all the members regardless of test volume. The emergence of large commercial laboratories has created market forces which drive down the fees laboratories charge and the amounts of PMPM rates. The economies of scale and the ability to have loss leaders for these larger laboratories have continued to put a strain on the viability and contribution margin in the laboratory industry. Laboratories will continue to need to think of new ways to grow revenue, such as supporting quality outcomes measures and developing new proprietary testing.

Gross versus Net Revenue

The bill a medical facility sends a patient or a patient's insurance company lists what is termed the "gross billing"

charges. Rarely are these gross billing charges paid in full. There are adjustments that are made (discounts) from the original charges based on the contractual payment agreements set up with various insurance payors. The original patient charge represents the gross revenue that is billed. The adjustments lower the gross revenue and determine the amount the medical facility should receive. This is the net revenue or expected dollars received. The difference between the gross revenue and the net revenue can be as much as 50 to 60%. A medical facility could bill a total of $100,000,000 for patient services but receive only $40,000,000 to $50,000,000.

Medicare

The Medicare program provides healthcare for the elderly and people with certain chronic diseases. Initially hospitals were paid based on their actual expenses for inpatient care for Medicare patients. In 1983 this all changed when the government instituted the prospective payment system, which reimburses hospitals based on DRGs for hospital inpatient services (Medicare Part A) (18). This system was based on reimbursing hospitals after Medicare patients were discharged and paying a set amount based on the discharge diagnosis. A major revision of the DRG system in 2007 resulted in more than 700 medical severity DRGs (MS-DRGs). If a hospital can treat a patient with a specific MS-DRG for less than it is reimbursed, then it makes money; if it costs more than the MS-DRG reimbursement, the hospital loses money. The government has instituted a similar program for outpatients with ambulatory payment classification (APC) (https://www.acep.org/administration/reimbursement/reimbursement-faqs/apc-ambulatory-payment-classifications-faq, accessed 12 September 2023) (31). Both the MS-DRG and APC systems have shifted the financial risk from the government to the provider.

Physician services and most non-physician outpatient services are paid by the Medicare Part B program based on a fee schedule. Over the years the Medicare Part B fee schedule for laboratory services has not kept pace with the medical price index, so the reimbursement for laboratory services by Medicare Part B has been decreasing in constant dollars.

Managed Care

Managed-care organizations are constantly negotiating with healthcare providers regarding reimbursement. They may pay a set fee for each day a patient is in the hospital (per diem). They may pay on a per-case basis, like Medicare DRGs. They may pay a set fee per month per member for any healthcare needed (capitated payment).

The net effect of the prospective payment system is a significant decrease in reimbursement and cash flow for providers. It does not appear that this trend will change soon. The payment for laboratory services reflects this trend, and reimbursements are usually less than half of the gross laboratory charges. As a result, the overall profit margin for laboratory services is decreasing.

Budgeting

The budget is a financial plan of operations. It is used to forecast anticipated revenues and expenditures over a period, typically 1 year. It provides a reference for the evaluation of financial performance of a department or the organization, and helps control costs. The budget is also a measuring stick for financial accountability. Supervisors or managers are generally held responsible for operating within their approved budgets. It is important to remember that the budget should be driven by the organization's strategic plan. It is for this reason that developing the budget should be a coordinated process between top organizational management and the department-level manager.

Operating Budget

An operating budget is a detailed projection of what an entity expects its revenue and expenses will be over a period. Operating budgets are usually completed annually. Companies complete an operating budget near the end of their budget year to plan for activity during the following year. There are various budgeting processes, with two of the most common types being incremental budgeting and activity-based or zero-based budgeting. Incremental budgeting is the traditional budgeting method where the budget is prepared by taking the current period's budget or actual performance as a base, with incremental amounts then being added for the new budget period. Activity-based (zero-based) budgeting is a system that records, researches, and analyzes activities for each cost the company incurs. Every activity in an organization that incurs a cost is scrutinized for potential ways to create efficiencies. Budgets are then developed based on these results.

Capital Budget

Capital budgeting is a process to determine which fixed asset purchases should be accepted. It involves identifying cash inflows and cash outflows rather than accounting revenues and expenses flowing from the investment. The process is used to create a quantitative view of each proposed fixed asset investment, thereby giving a rational basis for making a judgment. The prevalent methods include net present value analysis and payback period and replacement analysis. Present value is the current value of a future sum of money or stream of cash flows given a specified rate of return. Future cash flows are discounted at the discount rate, and the higher the discount rate, the lower the present value of the future cash flows. The payback period is the length of time it takes to recover the cost of an

investment or to reach a break-even point. Replacement analysis is the method used to decide whether the existing assets need to be replaced or not.

Revenue Cycle: Billing and Collecting

The revenue cycle starts with the office appointment, hospital visit, or other medical service provided and ends when the provider or hospital gets paid fully for the service. The seven steps of revenue cycle include preregistration, registration, charge capture, claim submission, remittance processing, accounts receivable (AR) follow-up, and patient collections. Preregistration is the first step before a patient visits a healthcare institution or healthcare provider. It is the process of obtaining each patient's demographic, health, and insurance information. Registration is finalizing the preregistration process once the patient arrives for service, to ensure all the required information is correct and complete. Charge capture is a process used to get paid for services provided. It is the process where healthcare providers record information for their services and then send it out to different payors and insurance companies for reimbursement. Claim submission is the process of determining the amount of reimbursement that the healthcare provider will receive from the insurance firm or grantor. Remittance processing is when a sum of money is sent from the insurance company or grantor back to the healthcare institution electronically. AR follow-up and patient collections ensure that healthcare organizations have a way to recover overdue payments. Most AR follow-up responsibilities include looking after denied claims, exploring partial payments, and reopening claims to receive maximum reimbursement.

More information on financial management, billing, coding, and reimbursement can be found in sections V, VI, and VII of this volume.

A Brief History of Clinical Laboratory Finances

After decades of profitability created by low direct costs, favorable inpatient reimbursement, hospital-based outpatient reimbursement, and physician utilization, the clinical laboratory industry suffered severe setbacks beginning in the 1990s and continuing into present times. Increased regulatory requirements and the expansion of managed care were the change drivers for many trends in the healthcare and clinical laboratory industries, as listed in Table 1.4 (16). Faced with possible loss of market share, commercial laboratories engaged in fierce competitive bidding for managed-care contracts, further decreasing laboratory reimbursement. At the same time, hospital laboratories faced excess testing capacity created by shifting STAT testing to point-of-care testing (POCT) and decreased inpatient lengths of stay. Laboratory managers have had to expand their focus to evaluating technical proficiency along with analyzing and controlling costs. Managers have strengthened their skills in human resource management, financial management, process improvement, and the creation of business plans. The industry has continued to observe record numbers of laboratory consolidations, mergers, acquisitions, and joint ventures during the past decades. Laboratory restructuring often followed hospital or healthcare system reorganization. Laboratory regionalization, first developed in the 1980s, focused on standardizing policies and procedures and providing improved continuity of care across multiple facilities and sites of care. This enhanced income by expanding the geographic market and lowered costs through economies of scale. This became a primary strategy in maximizing efficiency, thus reducing cost. Additionally, technological developments continue to improve productivity in the clinical laboratory. Laboratory services information is accessible globally, and laboratories are faced with international competition and greater pressures to reduce costs, increasing the commoditization of the clinical laboratory industry (32).

Table 1.4 Change drivers in healthcare and clinical laboratories[a]

Driver	Change
Tighter quality and documentation requirements (CLIA '88)[b]	Reduced test volume Increased cost of production
Increased coding and claims requirements	Reduced collections Increased denials
Reduced Medicare fee schedule	Reduced reimbursements
Managed-care enrollments more than doubled	Shift from fee for service to capitated reimbursement models
Fierce competitive bidding among commercial laboratories	Prices and reimbursements reached plateau, then decreased in 1990s

[a] See reference 21.
[b] Clinical Laboratory Improvement Amendments of 1988.

Managed care, pricing pressure, and capitated payment models, along with advances in medicine and technology, have created a constant state of change. Table 1.5 shows the typical paradigm shifts encountered by the laboratory industry over the past decade. A growing Baby Boomer population, more uninsured (or underinsured) patients, employees exiting the work force earlier, and employers balking at continuing to pay escalating premiums for healthcare coverage will cause many healthcare institutions to accept lower reimbursements. The downward trends in reimbursement will continue with even greater controls and limitations on utilization, forcing further reductions in the unit cost of medical services (reference 33, p. 170).

Management Ethics

Ethics is a very relevant issue in modern management. Every organization should espouse and live a clearly understood set of moral values and maintain the highest

Table 1.5 Industry trends during the past decades

Old paradigm	New paradigm
Centralized laboratory testing	Point-of-care testing (POCT)
	Near-patient and bedside testing
Physician office testing	Home testing kits
	Direct-access testing (DAT)
Laboratory-supervised phlebotomy	Patient-care technician at nursing stations
Inpatient procedures	Outpatient invasive procedures
Fee-for-service reimbursement (FFS)	Global payment systems Diagnosis-related groups (DRGs) Ambulatory payment classification (APCs)
Skilled hospital beds	Skilled-nursing facility (SNF) beds
Prospective payment system (PPS) for skilled-nursing facilities	Consolidated billing: services reimbursed under resource utilization groups (RUGs)
Standing orders	Patient care plans
Preventive healthcare screening and diagnosis V-codes	Medically necessary testing Local medical review policies (LMRP) Advanced beneficiary notices (ABNs)
Routine testing	Specialized esoteric testing
Top-down hierarchy	Bottom-up customer focus
Exceptional service	Creating value

possible standards. The *Complete Guide to Ethics*, an internet guide, provides an excellent resource for all matters relating to business and managerial ethics (http://www.managementhelp.org/businessethics/ethics-guide.htm; accessed July 2022). Ethics, speaking simply, involves knowing what is right and wrong, lessons presumably learned at an early age from parents and other guides (reference 8, p. 86).

Generally, business ethics problems center on two main themes: managerial mischief and "moral mazes" (reference 17, p. 255). Managerial mischief refers to illegal or questionable practices of individual managers or organizations, as well as the causes of those behaviors. A moral maze refers to the numerous and unclear ethical issues a manager faces in everyday work life (reference 34, p. 347–348). Examples here might be real conflicts of interest, wrongful use of resources, or mismanagement of contracts. What is right and what is wrong are not always clear in a competitive work environment.

Organizational vision and ethics come from the top (reference 17, p. 255). The organization's chief executive must support and underwrite an ethics program. Failure on the part of top management to actively and enthusiastically support an ethics program will be noted by the rank and file. The executive officer should champion the program's development and foster a climate that encourages ethical behavior. From the start, the senior officers must espouse honesty and integrity as primary operational traits. The most important step management must take regarding an ethics program is to fully promote it and never waver from the tenets accepted as organizational guidelines (reference 17, p. 255). A strong ethical framework must be one of the guiding tenets for the modern organization. The benefits of developing such a framework are many, whereas the downside can be severe. From the top to the bottom, all employees must accept and live the positive values their organization espouses, thus removing any uncertainty of where they stand with any moral dilemma.

SUMMARY

Leadership, management, and administration are not one and the same. At any moment, any one person may fill any of those roles. Learning what style fits you is a process of self-discovery and is shaped by the situation. The body of research and literature on management theory is broad, from a historical context as well as in terms of the number of those interested in the topic. There is no consensus on what theories present the best and most accurate picture of how to manage groups of people. As society moves forward and technology advances, management theory likewise expands and adapts to the new workplace. The ability to make good decisions often separates the best leaders and managers. Knowing how to work through to a good decision, keeping in mind the elements of time and risk, provides one of the solid bases for managerial success. A manager must develop a system to organize the workflow, policies, and staffing of the laboratory. They must also provide direction to the laboratory by communicating, delegating, motivating, and coaching. A manager must control the activities of the laboratory, constantly reviewing the current situation to ensure that there are no unattended details. There is no substitute for engaged leadership.

KEY POINTS

- Management and leadership are distinct and each serve essential functions. Leadership is an essential part of management. Managers lay down the structure and delegate authority and responsibility; leaders provide direction by developing the organizational vision.
- Management theory has evolved over time. Various models exist which can be applied to situations after consideration of the environment.
- Decision making is the process of making choices by identifying a decision, gathering information, and assessing alternative resolutions. Decision making is an integral part of modern management, with rational and sound decision making a primary function of management.

- Management is typically broken out into four primary areas: planning, organizing, directing, and controlling. Clinical laboratory models have continued to evolve. The balance between centralized and decentralized testing has shifted by institution based on financial considerations, speed of testing, accuracy of results needed, personnel resources, and scope of services.
- Financial management models have changed as revenue streams have evolved and testing models have changed, leading to cost variations.
- Laboratory processes have continued to change, and using proven management and leadership skills, along with qualitative financial analysis grounded in ethical practices, is needed for continued success.

GLOSSARY

Accountability An individual's obligation to be responsible for his or her own actions within the work environment.

Activity-based costing A method used by organizations that assigns a cost to every activity throughout the organization.

Administration Managerial work with a service orientation.

Behavioral theory Management theory based on shifting the focus from strictly organizational needs to the wants and needs of the individual worker.

Business ethics Learning and doing the right thing in the workplace, directly relating to products, services, and stakeholders.

Capital budgeting Process to determine which fixed asset purchases should be accepted.

Classical theory Management theory described by a group called classical theorists. Their work laid the foundation for management theory, in part by identifying the key managerial processes and the skills a manager needs to succeed.

Communication The exchange of information, flowing in all directions within the organization. It can be written or spoken, verbal or nonverbal, formal or informal.

Conflict of interest A situation in which a person has a private or personal interest sufficient to appear to influence the objective exercise of his/her duties.

Continuous/lifelong learning A self-empowering theory, that the employee will throughout his/her life learn and strive to improve and move on to new things.

Continuous quality improvement A more human-focused quality management theory, relying heavily on worker involvement in the product improvement process.

Core laboratory This term may refer to a main (central) laboratory within a multiple-laboratory system, or it may refer to a dedicated section within a single laboratory that does the majority of routine and STAT testing.

Cost center Unit within an organization whose primary purpose is to provide a service at the least possible cost.

Decision theory The study of how decisions are made and what guides a manager to a good decision.

Diagnosis-related groups (DRGs) Based on the discharge diagnosis, DRGs are a system developed by the federal government for prospective payment of Medicare inpatient services to providers.

Directing Planning a specific action and actively overseeing the execution of a plan.

Gross revenue The actual billed charges or fees for products and services before applying any adjustment for contractual arrangements for volume discounts, third-party limits of allowance, or direct and indirect expenses. Gross revenue is derived by multiplying the volume or quantity of services used by the unit price for the service.

Hierarchy of needs Defined by Maslow, from the most basic to the highest level, needs that must be addressed to motivate the employee.

Human relations movement An approach to management that focuses on the worker and his individual needs.

Intuitive decisions Utilization of hunches, subjective values, and personal or emotional factors in deciding what actions to take.

Judgmental decisions Conclusions reached after data are gathered, facts are analyzed, and concrete examples are explored.

Laboratory network A system (formal or informal) of clinical laboratories spread over a geographical area to provide laboratory services in a coordinated, integrated manner.

Leadership Influencing others to attain group, organizational, and societal goals.

Lean Management technique used to increase customer value while minimizing waste and using fewer resources.

Lean Six Sigma Combining Lean and Six Sigma theories for time and process efficiency.

Managed-care organization An organization formed by a third-party insurer as an alternative healthcare delivery system in an attempt to control the escalating costs of healthcare to large employer groups and the government.

Management Getting things done through other people.

Management by objectives Setting goals for the individual to achieve, dovetailing with larger organizational objectives.

Management science Management techniques based on mathematical models.

Medicare severity DRG (MS-DRG) Revised DRG system introduced in 2007.

Mission statement A written statement that clearly defines what the organization does and why it is important.

Moral maze Unclear ethical issues.

Net revenue Gross revenue minus contractual allowances and sales discounts.

Nonprogrammed decisions Unusual or atypical situational solutions.

Organizational chart A diagram showing relationships among functional areas within an organization.

Organizing The process of structuring resources and activities in a way that promotes the accomplishment of specific activities.

Operating budget Detailed projection of what an entity expects its revenue and expenses will be over a period of time.

Operations management Applied management technique, utilizing mathematical modeling and industrial engineering to promote efficiency and effectiveness.

Performance evaluation Formal feedback on job performance.

Point-of-care testing (POCT) Usually refers to tests performed near the patient. Often performed by a nonlaboratorian. POCT is frequently managed or overseen by clinical laboratory personnel within a larger organization.

Process reengineering Rethinking current work in favor of doing something new.

Profit Earnings above the expenditures for salaries, benefits, and direct and indirect costs.

Quantitative theory Management theory based on improving efficiency using a variety of metrics and strong quantitative approaches.

Revenue center Area of an organization which is responsible for generating a portion of the total revenues expected by the organization.

Revenue cycle Process of billing and collecting. The seven steps of the revenue cycle for medical services include preregistration, registration, charge capture, claim submission, remittance processing, accounts receivable (AR) follow-up, and patient collections.

Satellite laboratory A laboratory separated from the main laboratory, usually with a limited test menu, that is dedicated to a specific set of patients and/or locations in a medical facility.

Situational management Acting only on what needs to be addressed at a particular moment and recognizing that there is no best way to get a job done.

Six Sigma A highly disciplined process focusing on developing and delivering near-perfect products and services.

Standard operating procedures (SOPs) A written set of instructions that codify technical and administrative activity in the laboratory.

Strategic decision Focus on an organization's relationship with the external environment, competitive posture, and major policies.

Strategic planning A methodical and structured process whereby an organization defines its mission, identifies directions, develops a unified approach, prioritizes long- and short-term goals, assigns accountabilities, and allocates financial resources.

Strategy The technique, approach, or mechanics developed by the management team to facilitate the organization's ability to perform successfully.

SWOT analysis Analysis of the laboratory's strengths, weaknesses, opportunities, and threats. Strengths and weaknesses are often internal to the organization, while opportunities and threats are often externally derived.

Systems theory The merger of the theories from scientific management and the human relations movement.

Tactical decision Steps toward the implementation of organizational strategy.

Taylorism and scientific management An approach to work and the workplace where every job is divided into the smallest possible segments and each segment is examined and improved.

Theory X and theory Y Defined by McGregor, a theory highlighting the difference between those who believe people need to be forced to work versus those who believe people want to work.

Total quality management Designed-in product quality, with the focus on customer wants and needs as the key drivers in product and process improvement.

Vision statement A written statement that clearly and concisely articulates what the organization expects to become.

Workflow Tasks organized and accomplished in a particular way to achieve a specified result.

ACKNOWLEDGMENTS

The authors wish to acknowledge the work of Jeffrey Casterline, Ann Harris, Roxanne Mercer, John Snyder, Laurence Vetter, and David Wilkinson on chapters 1 through 4 in the 2nd edition of this book.

REFERENCES

1. **Merriam-Webster**. 2023. Administer. https://www.merriam-webster.com/.

2. **Taylor FW**. 1912. *Principles of Scientific Management*, p. 23–75. Van Nostrand, New York, NY.

3. **Fayol H.** 1949. *General and Industrial Management*. Pitman Publishing, New York, NY.

4. **Weber M.** 1921. *Theory of Social and Economic Organization*, p 328–333. (**Henderson AM**, **Parsons T**, translators.) The Free Press, Simon and Schuster, New York, NY.

5. **Mayo E.** 1933. *The Human Problems of an Industrial Civilization*, p 48–97. McMillan Publishing, New York, NY.

6. **Maslow A.** 1943. A theory of human motivation. *Psychol Rev* **50**:370–396.

7. **McGregor D.** 1960. *The Human Side of Enterprise*, p 33–48. McGraw Hill, New York, NY.

8. **Mescon MH**, **Albert M**, **Khedouri F**. 1985. *Management: Individual and Organizational Effectiveness*, 2nd ed. Harper and Row Publishers, Inc, New York, NY.

9. **Gulick L.** 1965. Management is a science. *Acad Manage J* **8**:7–13. https://www.jstor.org/stable/255127.

10. **Drucker PF**. 1954. *The Practice of Management*. Harper and Row, New York, NY.

11. Kast FE, Rosenzweig JE. 1972. General systems theory. *Acad Manage J* **4**:447–465.

12. Luthans F. 1973. The contingency theory of management: a path out of the jungle. *Bus Horiz* **6**:62–72.

13. Hatvany N, Pucik V. 1981. Japanese management practices and productivity. *Organ Dyn* **9**:5–21.

14. Riggs JL, Felix GH. 1983. *Productivity by Objectives*. Prentice-Hall, Englewood Cliffs, NJ.

15. Berry T. 1991. *Managing the Total Quality Transformation*. McGraw Hill, New York, NY.

16. Juran JM. 1995. *Managerial Breakthrough*, p 402–403. McGraw-Hill, New York, NY.

17. Kouzes JM, Posner BZ. 1995. *The Leadership Challenge*. Jossey-Bass, Inc, San Francisco, CA.

18. Berkowitz EN, Kerin RA, Hartley SW, Rudelius W. 2000. *Marketing*, 6th ed. McGraw-Hill, New York, NY.

19. Harvard Business Review. 1991. *Managing Product Life Cycles: From Start to Finish*, p 8–91. McGraw Hill, New York, NY.

20. Smith H, Fingar P. 2002. *Business Process Management: The Third Wave*. Meghan-Kiffer Press, Tampa, FL.

21. Burlton RT. 2001. *Business Process Management*, p 81–97. Sams Publishing, Indianapolis, IN.

22. Adams C, Gupta P, Wilson C. 2002. *Six Sigma Deployment*. Butterworth Heinemann, New York, NY.

23. Snyder JR, Hendrix BR. 1998. Problem-solving: the decision-making process, p 61–78. *In* Snyder JR, Wilkinson DS (ed), *Management in Laboratory Medicine*, 3rd ed. Lippincott-Raven Publishers, Philadelphia, PA.

24. Pickett RB. 2001. What does all of this leadership stuff mean to me? *Clin Leadersh Manag Rev* **15**:395–400.

25. Charns MP, Shaefer MJ. 1983. *Healthcare Organizations: A Model for Management*, p 223–249. Prentice-Hall, Inc, Englewood Cliffs, NJ.

26. Gill SL. 1995. Groups and decision making. *Clin Lab Manage Rev* **9**:464–470, 474–476.

27. Vroom VH, Jago AG. 1978. On the validity of the Vroom-Yetton model. *J Appl Psychol* **63**:151–162.

28. Giuliani RW. 2005. *Leadership*, p 123–154. Miramax Books, New York, NY.

29. Mackoff B, Wenet G. 2001. *The Inner Work of Leaders*, p 81–103. AMACOM, New York, NY.

30. Nolan T, Goodstein L, Goodstein J. 2008. *Applied Strategic Planning: An Introduction*. Pfeiffer, San Francisco, CA.

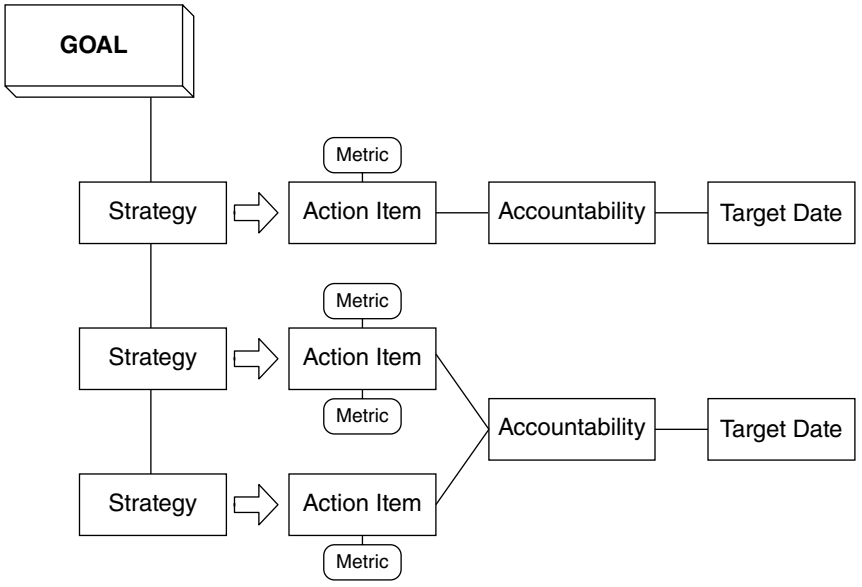
31. Johnson EA. 1989. Managerial-organizational communications. *In* Snyder JR, Senhauser DA (ed), *Administration and Supervision in Laboratory Medicine*, 2nd ed. Lippincott Williams and Wilkins, Philadelphia, PA.

32. Bossuyt X, Verweire K, Blanckaert N. 2007. Laboratory medicine: challenges and opportunities. *Clin Chem* **53**:1730–1733.

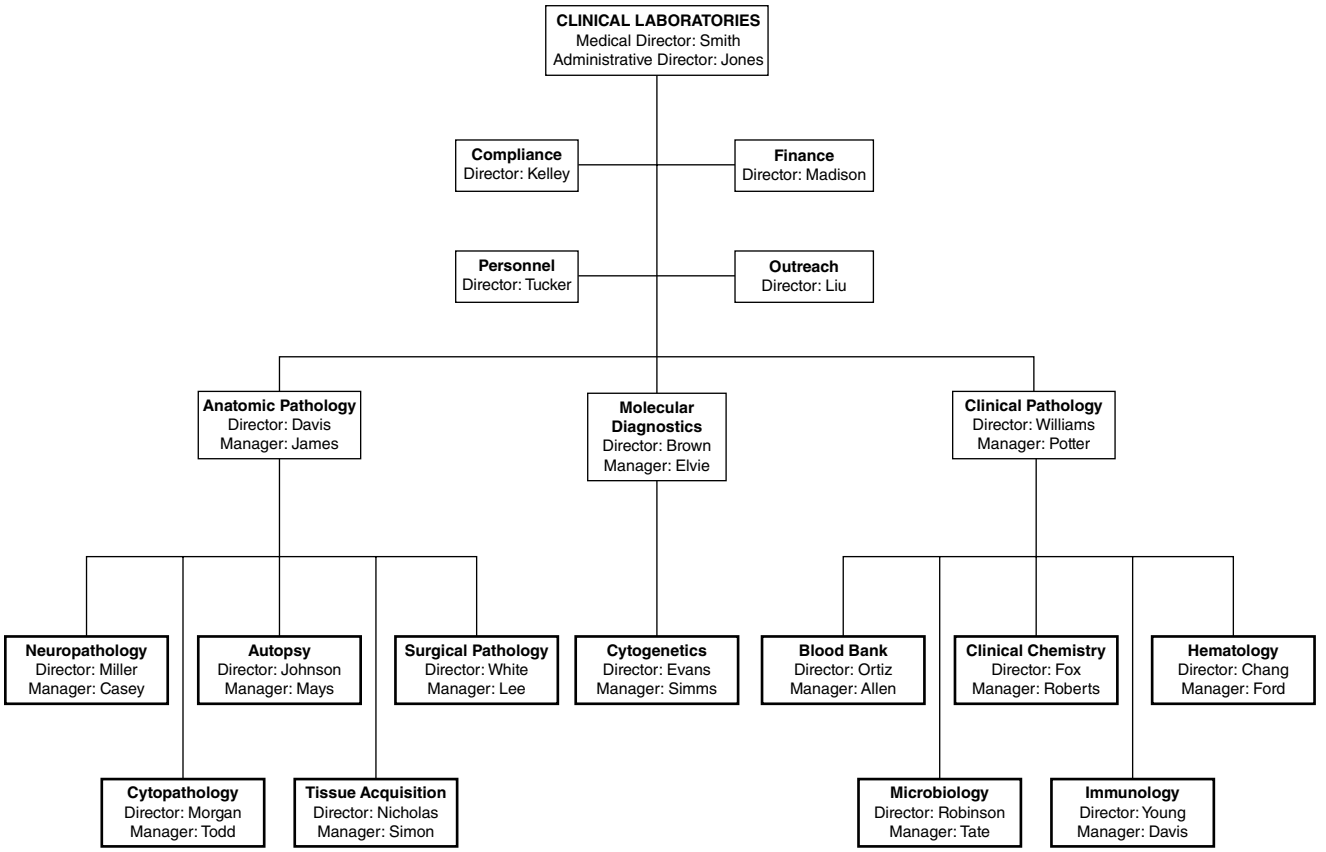
33. Nigon D. 1998. *Marketing in Your Laboratory*, 2nd ed. Clinical Laboratory Management Association, Inc, Wayne, PA.

34. Drucker PF. 1973. *Management: Tasks, Responsibilities, Practices*. Harper and Row, New York, NY.

APPENDIX 1.1 Laboratory Strategic Plan



APPENDIX 1.2 Laboratory Organizational Chart



2

Introduction

Brief History of Regulation of the Clinical Laboratory
Department of Health and Human Services and CLIA • FDA and Medical Devices

Overview of the Current Clinical Laboratory Regulatory Environment

CLIA and the Regulation of Quality
CLIA Framework • Quality Control

Accreditation and Licensure
Laboratory Inspection and Accreditation • Personnel Certification and Licensure

FDA Regulation of *In Vitro* Diagnostic Tests
Current Overview • Laboratory-Developed Tests

Regulations Affecting Transfusion Medicine
Introduction • Framework of FDA Regulations • Blood Collection and Component Production • Transfusion Services • Reporting Requirements • Cellular Therapies • Current and Future Regulatory Challenges

Clinical Laboratory Workplace Safety
Risk Assessments • Chemical Hazards • Biological Hazards • Other Infectious Hazards • Transportation of Clinical Specimens • Physical Hazards • Additional Safety Regulatory Resources

Overview of Laboratory Reimbursement Regulation
U.S. Healthcare • Medicare • Pathology and Laboratory Services in Medicare • Claims Processing • Reimbursement for Physician Services • Laboratory Test Reimbursement

Patient Privacy: HIPAA and Related Regulations
HIPAA Introduction • Protected Health Information • Patient Informed Rights • Consent and Authorization • Privacy Rule • Security Rule • HITECH and Omnibus Rule • Breach Notification Rule • Enforcement Rule • Current Topics in HIPAA Compliance • Summary of Laboratory Responsibilities

SUMMARY

KEY POINTS

GLOSSARY

ACKNOWLEDGMENTS

REFERENCES

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch2.

Regulatory Issues in Laboratory Medicine

Glenn Ramsey and Christina E. Anderson

OBJECTIVES

To gain an overall understanding of the regulatory requirements facing laboratories

To review the major elements of Clinical Laboratory Improvement Amendments of 1988

To understand how the Food and Drug Administration regulates laboratory tests

To present an overview of the regulatory oversight of transfusion medicine

To achieve compliance with laboratory safety standards

To introduce the framework of laboratory reimbursement requirements

To describe the laboratory requirements for patient health information confidentiality

> *Clinical laboratories are among the most highly regulated health care entities. Understanding the web of laws, regulations, and guidelines that affect laboratory practice is necessary to avoid legal or administrative repercussions that may limit a laboratory's operations or shut it down completely.*
>
> Tim Hilbert, Anthony Kurec, and Mark S. Lifshitz (1)

Compliance with regulatory requirements is a key element of clinical laboratory management. In the 1960s and 1970s, the United States adopted sweeping federal laws regulating healthcare, overseen by agencies in the Department of Health and Human Services (HHS). The Centers for Medicare and Medicaid Services (CMS) has regulatory oversight of clinical laboratories, their reimbursement by federal programs, and the privacy of patient health information. Medical devices (including *in vitro* diagnostics) and drugs (including blood transfusions) are under the jurisdiction of the Food and Drug Administration (FDA). The Department of Labor has primary responsibility for the regulation of employee workplace safety, including clinical laboratories. This chapter reviews the major elements of these regulations.

Brief History of Regulation of the Clinical Laboratory

Department of Health and Human Services and CLIA

Before Medicare was enacted in 1965, only 10 states required licensure of hospital laboratories and only three states licensed independent laboratories (2). The onset of a massive new federal healthcare program prompted concerns

about the quality of laboratory tests paid for by tax dollars. Congress heard testimony in 1967 that possibly up to 25% of U.S. laboratory tests were erroneous. Whether the overall error rate was really that high was controversial (3), but there were alarming examples of incorrect blood typings, misleading infectious disease tests, and an unscrupulous laboratory issuing reports on Papanicolau (Pap) smears it never read (2). The Clinical Laboratory Improvement Act of 1967 (CLIA '67) initiated federal licensure, inspections, and proficiency testing for (i) all laboratories engaged in interstate commerce and (ii) all hospital and independent laboratories receiving Medicare funds (3, 4). About 12,000 laboratories were included. Initially the interstate commerce laboratories were accredited by the College of American Pathologists (CAP) or, in New York, the state health department. The hospital Medicare laboratories were accredited in hospital inspections by the Joint Commission on Accreditation of Hospitals (now The Joint Commission [TJC]) and the independent laboratories by their state health departments.

However, many gaps in this oversight were publicized in a Pulitzer-Prize-winning series of articles in 1987 in the *Wall Street Journal* (5, 6). Hospital laboratories barred from Medicare reimbursement continued to perform non-Medicare testing. Physician office laboratories were regulated in only 13 states, and proficiency testing was usually not required or monitored. Inaccuracies in neonatal genetic tests, cancer biopsy interpretations, cholesterol levels, and workplace drug screens were spotlighted. Most infamously, some large commercial cytology laboratory operations were branded as "Pap mills," exploiting overworked and underpaid technologists to churn out dubious results which allegedly led to patient deaths after missed diagnoses.

Congress held hearings on laboratory oversight at the same time as HHS was proposing its own revisions to CLIA '67 (3). Ultimately Congress passed the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) and President Ronald Reagan signed Public Law 100-578 on October 31, 1988. After over 3 years and 60,000 public comments, the first complete version of the regulations was published in February 1992 (*Fed Reg* **57:**7002) (7). While cytology testing was especially emphasized, over 140,000 laboratories were subject to the new legislation.

It took several more years before CLIA '88 regulations became fully functional. From 1993 to 1995, several laboratory accreditation organizations were approved, including the CAP, TJC, the American Osteopathic Association (AOA), the Commission on Office Laboratory Accreditation (now COLA), the American Association of Blood Banks (now the Association for the Advancement of Blood and Biotherapies [AABB]), and the American Society for Histocompatibility and Immunogenetics (ASHI) (8). Laboratories regulated in Washington and New York states received ongoing exempt status because of equivalent state regulations.

Table 2.1 CLIA 1988: key amendments and recent requests for comments[a]

Date	*Fed Reg*	Topics
2/28/92	**57:**7002	CLIA 1988, original
1/19/93	**58:**5215	Provider-performed microscopy
4/24/95	**60:**20035	General supervisor and test personnel requirements
9/13/95	**60:**47534	Waived testing defined
5/14/98	**63:**26732	Proficiency testing; accreditation deemed status
12/30/99	**64:**73561	Test categorization of *in vitro* diagnostics transferred from CDC to FDA
1/24/03	**68:**3639	Broad rules reorganization; proficiency test grading
2/6/14	**79:**7290	Direct patient access to laboratory results
2/4/19	**84:**1536	Proficiency testing: proposed changes to required analytes and evaluation criteria
7/6/20	**85:**40290	Next-generation sequencing: request for comments on personnel qualifications and data file retention
9/2/20	**85:**54873	COVID-19 test reporting
7/26/22	**87:**44896	Histocompatibility technical updates; changes to educational qualifications for non-physician laboratory directors and other personnel

[a] *Fed Reg*, Federal Register (https://www.federalregister.gov/ [7]); CLIA, Clinical Laboratory Improvement Amendments of 1988; CDC, Centers for Disease Control and Prevention; FDA, Food and Drug Administration.

Table 2.1 outlines some key amendments and rule changes to CLIA '88 over the next 30 years. Waived testing was defined in 1995. The trend over the years has been to clarify and streamline rules to address changes in technology and challenges encountered by the healthcare system.

Some areas of potential future changes have emerged in recent years. CMS asked for comments on updating histocompatibility testing regulations in 2018, and on personnel and record-keeping requirements for next-generation sequencing in 2020. Important changes in proficiency testing requirements were published in 2022, to be fully effective in 2024.

FDA and Medical Devices

The Federal Food, Drug, and Cosmetic Act of 1938 brought medical devices under the drug regulations, but only to the extent of preventing adulteration or misbranding (9, 10). Shortly after the FDA blocked approval of thalidomide because of teratogenicity, the Drug Amendments of 1962 codified FDA premarket approval of drugs based on evidence of safety and efficacy. In the 1970s the need arose for more specific regulation of medical devices in the wake of problems such as faulty pacemakers, intraocular

lens infections, and fatal complications from an intrauterine device (Dalkon Shield). The Medical Device Amendments of 1976 established the general regulatory framework for medical devices, described in more detail later.

The Safe Medical Devices Act of 1990 defined substantial equivalence for 510(k) applications based on precedents from prior devices (10). It also mandated more extensive adverse event reports to the FDA, with recalls and civil penalties when needed. In 1997 exemptions to 510(k) clearance were expanded, and in 2002 user fees for applicants were established.

Overview of the Current Clinical Laboratory Regulatory Environment

Table 2.2 outlines broad elements of laboratory operations and shows their main regulatory agencies. CMS via CLIA '88 regulates clinical laboratory operations to help ensure quality results. Although the regulatory agencies overseeing clinical laboratory testing and pathology services generally work separately, there is some overlap in their oversight. Some federal oversight is delegated to certain states based on those states' regulatory systems matching or surpassing the relevant federal rules.

CLIA and the Regulation of Quality

CLIA Framework

Regulation of clinical laboratories began in earnest soon after the Medicare and Medicaid laws went into effect in 1966. The Clinical Laboratory Improvement Amendments of 1967 (CLIA '67) established minimum quality standards for Medicare-participating laboratories engaged in interstate commerce, a relatively small portion of clinical laboratories. Lawmakers soon saw the need to regulate all laboratories engaged in testing human specimens. Thus began the effort to amend CLIA '67 to establish minimum standards for personnel, accuracy, and quality control and to mandate inspections. When the CLIA '67 final rule was enacted in 1978, it included rules for quality control, proficiency testing, and personnel competency. Personnel working in laboratories receiving Medicare reimbursement were required to be medical technologists with a bachelor's degree or equivalent or to demonstrate satisfactory performance on a proficiency exam administered by Health, Education and Welfare, the precursor to Health and Human Services.

The enactment of CLIA '88 brought virtually all laboratories doing clinical testing for diagnosis or disease management on human specimens under the umbrella of federal regulation. This more comprehensive law required all laboratories doing human clinical testing to have a certificate issued by the HHS Health Care Financing Administration, now known as CMS (11). The final 1992 CLIA regulations are based on the complexity of the test method; thus, the more complicated the test, the more stringent the requirements. Three federal agencies have a responsibility to ensure quality laboratory testing under CLIA, each with a specific role (Table 2.3). The FDA, under CLIA, has established three categories of *in vitro* diagnostic tests: waived complexity; moderate complexity,

Table 2.2 Overview of the laboratory regulatory environment[a]

Elements of laboratory operations	Main regulatory agencies (Acts)
Laboratory quality: test performance, personnel qualifications, facility	CMS (CLIA '88) States of Washington and New York
Medical information privacy	HHS Civil Rights (HIPAA)
Medical workplace safety	Dept. of Labor, OSHA
Analytic and clinical validity of *in vitro* diagnostic tests	FDA
Blood transfusions as drugs	FDA
Diagnosis-appropriate laboratory testing and reimbursement	CMS for federal programs States for state programs
Appropriate medical business practices	HHS Inspector General

[a] CLIA, Clinical Laboratory Improvement Amendments of 1988; CMS, Centers for Medicare and Medicaid Services; FDA, Food and Drug Administration; HIPAA, Health Insurance Portability and Accountability Act; HHS, Department of Health and Human Services; OSHA, Occupational Safety and Health Administration.

Table 2.3 CLIA federal agency responsibility[a]

Food and Drug Administration (FDA)
- Categorizes tests based on complexity
- Reviews requests for waiver by application
- Develops rules/guidance for CLIA complexity categorization

Centers for Medicare and Medicaid Services (CMS)
- Issues laboratory certificates
- Collects user fees
- Conducts inspections and enforces regulatory compliance
- Approves private accreditation organizations for performing inspections and approves state exemptions
- Monitors laboratory performance on proficiency testing (PT) and approves PT programs
- Publishes CLIA rules and regulations

Centers for Disease Control and Prevention (CDC)
- Provides analysis, research, and technical assistance
- Develops technical standards and laboratory practice guidelines, including standards and guidelines for cytology
- Conducts laboratory quality improvement studies
- Monitors proficiency testing practices
- Develops and distributes professional information and educational resources
- Manages the Clinical Laboratory Improvement Advisory Committee (CLIAC)

[a] https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia (128).

Table 2.4 Examples of waived, moderate-complexity, and high-complexity tests[a]

Waived
Pregnancy test
Rapid strep test
Fecal occult blood
Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use
Spun hematocrit
Moderate complexity
Urine culture and colony count kits
Manual procedures with limited steps and with limited sample or reagent preparation
Automated procedures that do not require operator intervention during the analytic process
High complexity
Manual cell counts
Serogrouping and typing
Hemoglobin electrophoresis
Western blot
Flow cytometry
Cytopathology examinations

[a] The Food and Drug Administration website provides additional information on grading of test complexity at https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-categorizations (accessed 8 May 2023) (129).

Table 2.5 Types of laboratory CLIA certificates[a]

Certificate of waiver. Issued to a laboratory to perform only waived tests.
Certificate for provider-performed microscopy procedures (PPMPs). Issued to a laboratory in which a physician, midlevel practitioner, or dentist performs no tests other than the microscopy procedures. This certificate permits the laboratory to also perform waived tests. Examples of PPMPs include fern testing, microscopic urinalysis, nasal smears for eosinophils, and wet mounts, including preparations of vaginal, cervical, or skin specimens.
Certificate of registration. Issued to a laboratory and enables the entity to conduct moderate- or high-complexity laboratory testing or both until the entity is determined by survey to be in compliance with the CLIA regulations.
Certificate of compliance. Issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable CLIA requirements.
Certificate of accreditation. Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by the CMS.

[a] Information about the various types of CLIA certificates is available at the Centers for Medicare and Medicaid Services website (www.cms.gov/clia [accessed 8 May 2023]). See also https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCLIACertificate.pdf (130).

including the subcategory of provider-performed microscopy procedures (PPMPs); and high complexity (Table 2.4). Waived laboratories must enroll in CLIA, pay the applicable fee, and follow manufacturers' instructions. Because problems in cytology laboratories were the impetus for CLIA, there are also specific cytology requirements (42 CFR 493) (12). Before the CMS grants a certificate, laboratories must register, pay fees, and be surveyed. Moderate- and high-complexity laboratories have the option of choosing to be surveyed by the CMS or by a private accrediting organization that has been granted "deemed status" (Table 2.5).

CLIA '88 regulations specify quality standards for policies and procedures, proficiency testing, patient test management, quality control, personnel qualifications, and quality assurance for laboratories performing moderate- and/or high-complexity tests. Standards for quality assurance include monitoring the entire preanalytic, analytic, and postanalytic testing process.

Quality Control

As a first attempt at alternative quality control (QC) practices, CMS published interpretive guidelines for Equivalent Quality Control (EQC) for nonwaived testing in 2004. This optional program allowed for a reduction in frequency of daily external QC testing for eligible test systems that were deemed stable and easy to use, with infrequent occurrences of QC failures. There were disadvantages to this program, as it had limited scope and largely fell short of conditions to meet regulatory expectations (13).

As the technology of instrumentation and testing processes continued to evolve, CMS introduced a risk-based QC program in 2014. After an introductory period of education and training, the Individualized Quality Control Program (IQCP) was implemented in 2016 under 42 CFR 493.1256 Standard: Control Procedures (12). IQCP is a voluntary quality control program in which laboratories can opt to reduce the frequency of performing QC. The alternative is to continue performing QC following CLIA regulations. Frequency of QC performance for qualitative testing includes at least a positive and negative control each day of testing. Quantitative testing guidelines required two controls at different concentrations at least daily, with blood gas and coagulation testing requiring additional performance frequencies.

An IQCP includes three parts: risk assessment, quality control plan, and quality assessment. The most important part is risk assessment, which considers the entire testing process and includes mandatory review of specimens, environment, reagent, test system, and testing personnel (Table 2.6). Once implemented, a periodic assessment of the plan should routinely be performed and be reevaluated whenever there is a change to the testing process (14). Comprehensive information on the CLIA program, including the IQCP, is located on the CMS website (15).

Table 2.6 Individualized Quality Control Plan (IQCP) elements[a]

Element	Definition	Notes
Risk Assessment (RA)	Identification and evaluation of the source of failures and errors within a testing process. • Specimen • Test system • Reagents • Environment • Testing personnel	RA applies to the test system. Consider all variables when performing the assessment.
Quality Control Plan (QCP)	Written processes and procedures to reduce the likelihood of failures and errors	Applies to the individual device QCP can be developed for an individual device OR for multiple sites under one CLIA.
Quality Assessment	An ongoing assessment of the effectiveness of the QCP	Review preanalytical, analytical, and postanalytical quality monitoring records.

[a] Sources: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf; https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure13.pdf (references 131 and 132).

Accreditation and Licensure

Laboratory Inspection and Accreditation

The type of CLIA certificate held by the laboratory determines whether routine inspections are required. Routine inspections are not required for laboratories registered with a certificate of waiver or a certificate for provider-performed microscopy procedures (PPMPs). Over time the number of waived laboratories has increased to 80% of the total laboratories enrolled. Combined with the 9% of enrolled laboratories that hold a PPMP certificate, 89% of all laboratories do not have routine inspections or oversight (16) (see Tables 2.4 and 2.5). Random inspections are conducted at a small percentage of waived and PPMP laboratories each year. These inspections focus on ensuring that the laboratories are not performing testing at a higher level than their certificate warrants and that they are following other CLIA regulations. Pilot studies conducted during 1999–2001 in 10 states found significant problems with quality and certification (laboratories testing beyond their certificate). As a result, in 2002, the CMS began on-site educational and information-gathering visits to approximately 2% of waived laboratories. The CMS currently has no plans to increase the percentage of site visits to waived laboratories (http://www.cms.gov/clia [accessed 8 May 2023]).

Laboratories performing moderate- or high-complexity testing are required to have an inspection every 2 years. The laboratory may opt to be inspected by the CMS or by an organization that has been approved by the CMS (granted deemed status) as having program requirements at least as stringent as CLIA. The CMS awards a certificate of compliance to laboratories that are successfully inspected by the CMS and a certificate of accreditation to laboratories based on a successful inspection by an organization having deemed status with the CMS (Table 2.7). A provision of CLIA '88 exempts from CLIA requirements "all State licensed or approved laboratories in a State that has a State licensure program established by law" if the state licensure requirements are at least as stringent as the CLIA requirements. Two states, Washington and New York, are currently exempt (17).

As noted above, before the CMS grants deemed status to an organization's laboratory inspection program, the organization must show that the inspection criteria used

Table 2.7 Accrediting organizations with deemed status under CMS[a]

AABB (Association for the Advancement of Blood & Biotherapies, formerly American Association of Blood Banks)
4500 Montgomery Avenue, Suite 700, North Tower, Bethesda, MD 20814
301-907-6977
www.aabb.org (accessed 8 May 2023)

American Association for Laboratory Accreditation
5202 Presidents Court, Suite 220, Frederick, MD 21703
301-644-3248
https://a2la.org/ (accessed 8 May 2023)

Accreditation Commission for Health Care, Inc.
139 Weston Court, Cary, NC 27513
855-937-2242
https://www.achc.org/ (accessed 8 May 2023)

American Society of Histocompatibility and Immunogenetics
1120 Route 73, Suite 200, Mt. Laurel, NJ 08054
856-335-3299
www.ashi-hla.org (accessed 8 May 2023)

COLA (formerly the Commission on Office Laboratory Accreditation)
9881 Broken Land Parkway, Suite 200, Columbia, MD 21046-3016
800-981-9983
www.cola.org (accessed 8 May 2023)

College of American Pathologists
325 Waukegan Road, Northfield, IL 60093-2750
Laboratory Accreditation Program
800-323-4040, 847-832-7000
www.cap.org (accessed 8 May 2023)

The Joint Commission
One Renaissance Boulevard, Oakbrook Terrace, IL 60181
630-792-5800
www.jointcommission.org (accessed 8 May 2023)

[a] The Centers for Medicare and Medicaid Services maintains a current list of accrediting organizations with deemed status at its website (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Accreditation_Organizations_and_Exempt_States [accessed 8 May 2023]).

are at least as stringent as those of the CLIA program. Thus, the basic focus of all accredited inspection programs is to ensure compliance with the CLIA standards. However, organizations that have deemed status use different approaches to achieve that goal.

Centers for Medicare and Medicaid Services (CMS). Laboratories inspected under the CMS program experience an outcome-oriented survey process. CMS inspections utilize a quality assurance focus combined with an educational approach to assess and ensure compliance. General information about the CLIA program and Interpretive Guidelines for Laboratories can be found on the CMS website (18).

The Joint Commission (TJC). Experienced in surveying laboratories since 1979, TJC gained deemed status in 1995. TJC surveys are conducted by experienced medical technologists who provide consultation on performance improvement throughout the survey process. TJC's laboratory survey process is further explained on the organization's website at https://www.jointcommission.org/accreditation-and-certification/health-care-settings/laboratory-services/ (accessed 8 May 2023).

College of American Pathologists (CAP). The CAP laboratory inspection and accreditation program encompasses all of the laboratory disciplines. It provides the most comprehensive offerings of any of the accrediting bodies. Conducted as a peer-review process, inspections are performed by experienced working laboratory professionals. The peer review process provides the opportunity for laboratories to learn both from their own inspection and from the experience of inspecting other laboratories. CAP has deemed status with both CLIA '88 and TJC. Detailed information about the CAP inspection program is available on the CAP website, https://www.cap.org/laboratory-improvement/accreditation (accessed 8 May 2023).

COLA. Formerly known as the Commission of Office Laboratory Accreditation, but now known by its acronym, COLA is a nonprofit, physician-directed organization. COLA was founded in 1988 to provide a private alternative for complying with CLIA '88. Originally established to inspect physician office laboratories (POLs), COLA's accreditation program now covers many types of laboratories, from POLs to community hospitals and industrial laboratories. COLA inspections are conducted in an educational and friendly peer-review process. COLA has had deemed status with CLIA '88 since 1993. Laboratories interested in COLA accreditation can find more information at the organization's website at http://www.cola.org (accessed 8 May 2023).

Accreditation Commission for Health Care (ACHC). The ACHC took over the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) in 2021. AOA/HFAP had deemed status under CLIA '88 to accredit laboratories that are in AOA-accredited hospitals, but the ACHC does not focus on osteopathic healthcare facilities. Their portfolio includes accreditation of clinical laboratories. The ACHC website has more information (https://www.achc.org/clinical-laboratory [accessed 8 May 2023]).

American Association for Laboratory Accreditation (A2LA). The A2LA's main focus is the industrial laboratory setting, but it is approved by CMS for clinical laboratory accreditation. A2LA includes International Organization for Standardization (ISO) standards in its laboratory evaluations (https://a2la.org/accreditation/clinical-testing/ [accessed 8 May 2023]).

Association for the Advancement of Blood and Biotherapies (AABB). The AABB (formerly the American Association of Blood Banks) has been developing voluntary compliance standards for blood banking since 1957. AABB inspections have deemed status under CLIA '88. The inspections are based on compliance with federal regulations and documents as well as AABB standards (https://www.aabb.org/standards-accreditation/accreditation [accessed 8 May 2023]).

American Society of Histocompatibility and Immunogenetics (ASHI). The ASHI conducts a voluntary inspection program encompassing over 200 histocompatibility laboratories. ASHI's laboratory accreditation program has been evolving since 1976. Deemed status with CLIA '88 was granted in 1995 and with TJC and the states of Florida, Oregon, and Washington in 1997. ASHI's accreditation program evaluates facilities to ensure compliance with ASHI standards. Laboratory procedures, staff, and facilities are surveyed with an emphasis on education and assistance with correcting deficiencies. The ASHI website (http://www.ashi-hla.org [accessed May 8, 2023]) provides more information about the ASHI accreditation process.

Foundation for the Accreditation of Cellular Therapy (FACT). FACT, while not granted deemed status under CLIA '88, sets voluntary standards and accredits laboratories in the field of cellular therapy. Previously known as the Foundation for the Accreditation of Hematopoietic Cell

Therapy, FACT is a nonprofit corporation that establishes standards covering all phases of cellular therapy. FACT accredits programs and laboratories voluntarily meeting these standards. Information about FACT accreditation can be found at https://www.factglobal.org/accreditation-process (accessed 8 May 2023).

Laboratories exempt from CLIA '88. The CLIA '88 law states that laboratories will be cited as out of compliance unless they have a "current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPMPs, or a certificate of accreditation" or are CLIA exempt.

Laboratories falling under the exempt category include:

- Laboratories performing forensic testing only.
- Research laboratories testing human specimens but not using patient-specific results in the diagnosis, prevention, treatment, or assessment of disease or health of individuals.
- Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA). This exemption applies only to drug testing meeting SAMHSA guidelines and regulation (all other testing is subject to CLIA regulations).
- Federal laboratories under the jurisdiction of an agency of the federal government are subject to CLIA regulations unless the application is modified by the secretary.
- Laboratories licensed in states that have their own inspection programs as rigorous as CLIA. Washington and New York are the only two states currently in this category.

Information regarding laboratories exempt from CLIA regulations may be found in 42 CFR 493.3 (12).

Personnel Certification and Licensure

Certification is a voluntary program, usually administered by a professional association or governmental agency, recognizing an individual for having met predetermined criteria as set by that organization (19). Certification programs began as a voluntary method of demonstrating competence and enhancing competitiveness in the job market. Current CLIA '88 regulations emphasize specific education and experience, rather than certification, for the various levels of testing complexity. In general, the requirements of certifying organizations are more stringent than those of CLIA '88 (20).

Licensure is the process of a governmental authority granting an individual legal permission to engage in a specific practice. Typically, licenses are granted after examination or proof of specific education. The public is protected from incompetent practitioners by defining regulated practices and making unlicensed practice illegal (19).

Personnel requirements under CLIA '88. The personnel regulations under CLIA '88 do not rely on either certification or licensure, although some states may require either or both. The CLIA '88 personnel requirements are determined by the level of testing complexity. There are no personnel requirements for waived testing. For PPMPs and moderate- or high-complexity testing, CLIA '88 personnel regulations define specific job titles and associated qualifications and responsibilities (Table 2.8). The regulations spell out several ways an individual may qualify for each of the job titles, with the qualifications growing slightly more stringent as complexity increases. Only laboratory directors are limited in the number of lab affiliations. Each director may direct no more than five nonwaived laboratories.

Qualifications and responsibilities are delineated for the laboratory director and testing personnel at each testing level. For moderate-complexity certificates, the titles of Technical Consultant and Clinical Consultant are added. In addition to the laboratory director and testing personnel, high-complexity laboratories must also have a technical supervisor, clinical consultant, and general supervisor.

Proposed changes to personnel requirements. In July 2022, CMS proposed modifications to the qualifications for laboratory directors, technical supervisors, and general supervisors (*Fed Reg* **87:**44896) (141). The proposals would reflect evolution of healthcare-related educational requirements and degrees over the previous 30 years.

National certifying organizations. Certification by a professional agency is valued (and in many cases required) by employers because it is a demonstration of basic competence in the area of examination. There are several options for certification as a laboratory professional. The majority of graduates of programs accredited by the National Accrediting Agency for Clinical Laboratory Sciences choose to take a certification examination.

The ASCP, an organization of pathologists and other clinical laboratory personnel, was the first organization to offer a certifying examination. Responding to a need for programs that would allow documentation of the basic competence of laboratory workers, the ASCP established the Board of Registry in 1928 to certify nonphysician laboratory personnel. The ASCP Board of Registry offers a voluntary program to recognize competence based on documentation of 60 hours of continuing education, obtaining a higher level of certification (specialist or diplomate), or an onsite assessment completed by a supervisor. The ASCP Board of Registry certification program

Table 2.8 Personnel responsibilities and qualifications under CLIA '88[a]

Personnel and responsibilities	Degree[b]	Training or experience	Other experience
Provider-performed microscopy			
Lab director	MD, DO, DDS, midlevel practitioner		
Overall operation and administration			
Testing personnel	MD, DO, DDS, midlevel practitioner		
Moderate-complexity testing			
Lab director	MD, DO	Pathology board-eligible	
Overall operation and administration	MD, DO, DPM	20 h in lab CME or residency training or:	1 yr direct or supervise
	Doctoral*	Board-certified or:	1 yr direct or supervise
	Master's*	1 yr lab training or experience, and:	1 yr supervise
	Bachelor's*	2 yr lab training or experience, and:	2 yr supervise
Technical consultant	MD, DO	Pathology board-eligible	
Technical and scientific oversight	MD, DO, DPM, doctoral or master's	1 yr lab training or experience	
	Bachelor's	2 yr lab training or experience	
Clinical consultant	MD, DO		
Patient care consultant for clients	Doctoral	Board-certified	
Testing personnel	Associate* or higher		
Specimen process, test, report	High school and:	Training for testing, including military	
High-complexity testing (HCT)			
Lab director	MD, DO	Pathology board-eligible	
Overall operation and administration	MD, DO, DPM	1 yr lab training in residency or:	2 yr direct HCT
	Doctoral	Board-certified	
Technical supervisor	MD, DO	Pathology board-eligible, both AP and CP	
Technical and scientific oversight	Or within each lab specialty:		
	MD, DO	CP board-eligible	
	MD, DO, doctoral	1 yr lab training or experience, including:	≥6 mo in specialty HCT
	Master's	2 yr lab training or experience, including:	≥6 mo in specialty HCT
	Bachelor's	4 yr lab training or experience, including:	≥6 mo in specialty HCT
	Lab-specific details: 493.1449		
Clinical consultant	MD, DO		
Tests appropriate and interpreted	Doctoral	Board-certified	
General supervisor	MD, DO, or DPM	1 yr lab training or experience	
General supervision, day-to-day	Associate or:	Training equivalent (see 493.1489) and:	2 yr in HCT
Testing personnel	Bachelor's or above		
Specimen process, test, report	Associate or:	Training equivalent	
	Lab-specific details: 493.1489		

[a] All qualifications are a partial list. More details at 42 CFR 493 Subpart M (493.1351-1495) (12). Some changes to these qualifications were proposed by CMS in July 2022 (*Fed Reg* **87:**44896) (141).

[b] *, Degrees in appropriate fields: AP, anatomic pathology; CME, continuing medical education; CP, clinical pathology; DO, doctor of osteopathy; DDS, doctor of dentistry; DPM, doctor of podiatry; MD, doctor of medicine.

has expanded from its initial offering of the medical technologist exam to its current offering of 21 different certifications (21).

In 1978 the National Credentialing Agency (NCA) offered its first credentialing examinations (21). A voluntary, not-for-profit organization, NCA offered the "only peer-developed and peer-administered examination for medical laboratory personnel." In 2009 ASCP and NCA merged to form a single certification agency. Laboratory personnel previously certified by the NCA are now certified through ASCP (22). ASCP certifications must be renewed every 3 years by documenting completion of specified continuing education.

Other organizations offering certification include the American Medical Technologists (AMT) and the American Association of Bioanalysts (AAB). AMT offers certification in six areas of laboratory practice. Individuals with an appropriate bachelor's degree and 1 year of laboratory experience are eligible to sit for the medical technologist certification exam (https://americanmedtech.org/ [accessed 8 May 2023]). The AMT medical technologist certification may be awarded in some circumstances without taking the examination. The AAB Board of Registry requires the applicant to pass an examination that the AAB deems acceptable and to meet one of several education and/or experience requirements. Information can be found at www.aab.org/aab/Certification.asp (accessed 8 May 2023).

States requiring licensure/certification. While certification demonstrates a basic level of competence that may make it easier to get a job, as of this writing 10 states (California, Florida, Hawaii, Louisiana, Montana, Nevada, New York, North Dakota, Tennessee, and West Virginia) and one territory (Puerto Rico) also require that laboratory personnel obtain state licensure. Requirements for obtaining a state license vary by state but usually include a licensing fee, documentation of certification, some evidence of continuing education, and demonstration of education and competency as defined by the state. Most states accept certification from a recognized certifying organization. The exception is California, which administers its own examinations and does not recognize any certification or grant reciprocity for any other state's license. Requirements for state licensure may change. The most current information is available at the American Society for Clinical Laboratory Science (ASCLS) website (https://ascls.org/licensure/ [accessed 8 May 2023]).

Some states and U.S. territories require that laboratories operating within their borders, and in many cases performing testing on samples from that state, obtain a license from that state or territory. CMS maintains a list of state and territory laboratory licensure programs (23). However, because the number of states requiring laboratory licensure is fluid, an individual laboratory is advised to contact the appropriate state survey agency for the most current information.

FDA Regulation of *In Vitro* Diagnostic Tests

Current Overview

The FDA regulates *in vitro* diagnostic (IVD) tests as medical devices (24). (The Glossary at the end of this chapter provides terms and definitions used in the following discussion.) The 1976 Medical Devices Act and its subsequent amendments categorized medical devices into classes I, II, and III based on risk. Quality system regulations and general controls apply to all devices and are sufficient for many simple low-risk IVD tests.

The next layer of review is 501(k) approval, named after its CFR section. 501(k) approval from FDA refers to demonstration of "substantial equivalence" to a previously approved device [FDA 501(k) guidance 2014]. Class I devices are low to moderate in risk; most are exempt from 501(k) approval. Class II devices pose moderate to high risk and require both general and special controls; most also require 501(k) approval. Most IVD tests are in class I or II.

Class III devices pose high risks if results are incorrect. They are not eligible for 501(k) approval and must undergo premarket approval (PMA) by the FDA. The ratio of 501(k) to PMA IVDs is about 50:1. A few product types were grandfathered in from before 1976 and do not have a class designation. Blood donor infectious disease screening tests are approved by a different pathway.

The FDA provides several databases to search for medical device review and approval information (Table 2.9). The CLIA database can search for all manufacturers testing any given analyte. Users of the Product Classification Database can find the product code applying to devices used for a specific purpose such as an IVD test. For example, in the Hematology device panel, the partial thromboplastin time test has product code GGW (class II). The Establishment Registration and Device Listing provides searches by product code, device name, or manufacturer. The Manufacturer and User Facility Device Experience (MAUDE) is searchable for all medical device reports to FDA of malfunctions which could have led to or are suspected of causing death or serious injuries.

Laboratory-Developed Tests

Laboratory-developed tests (LDTs) include a wide range of assays, from FDA-approved tests which are slightly modified to esoteric tests in reference laboratories. Proposed FDA regulation of LDTs is a long-simmering issue which found new urgency in the COVID-19 pandemic. As far back as 1992 and 2010, the FDA declared intent to regulate

Table 2.9 Selected FDA device databases[a]

Database	Usage notes and examples
Medical Device Databases (133): https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases	Listing of all FDA medical device databases
CLIA Database (134): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm	Select analyte from dropdown menu. CLIA test complexity and all manufacturers are displayed.
Product Classification Database (135): https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database	Look up three-letter product codes. Choose Review Panel from dropdown (e.g., Hematology). Review all product codes to find desired product code.
Establishment Registration and Device Listing (136): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm	Search for devices by establishment or owner name, product code, or classification device name.
MAUDE—Manufacturer and User Facility Device Experience (137): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM	Search by manufacturer or product class for medical device reports to FDA of deaths, serious injuries, or malfunctions which could have led to these.

[a] CLIA, Clinical Laboratory Improvement Amendments. According to FDA, the following may not operate correctly for these databases: Apple Mac computers, wide-screen monitors, Firefox, Google Chrome, Internet Explorer 8.0 (https://www.fda.gov/medical-devices/device-registration-and-listing/important-reminders-about-registration-and-listing [138]).

LDTs, but enforcement was deemed discretionary (25, 26). A draft guidance in 2014 proposing guidance-based development generated numerous professional and legal comments (27). In 2017 the FDA issued a Discussion Paper after determining that new law was needed (28). Regulatory hurdles encountered in the rapid development of COVID-19 tests under emergency use authorization spotlighted the need for resolving this issue. More recent efforts mostly coalesced around the Verifying Accurate Leading-edge IVCT (*in vitro* clinical test) Development (VALID) Act (29, 30). In May 2022 the Senate inserted the VALID Act into a larger bill, the FDA Safety and Landmark Advancements (FDASLA) Act (Senate Act 4348) (31). The FDASLA was eventually passed by Congress in December 2022, but only after all ancillary provisions, including the VALID Act, were removed. In response to the lack of legislation, the FDA announced that it would begin working to regulate LDTs using its existing authority, through the regulatory rulemaking process (32).

Regulations Affecting Transfusion Medicine

Introduction

In 1970 the U.S. Congress added "blood, blood components and derivatives" to the regulatory purview of the FDA (33). During the 1970s, regulations evolved for FDA licensure, regulation, and inspections of blood banks. In response to the high rate of transfusion-transmitted hepatitis, state health departments and then the FDA required labeling to distinguish paid from volunteer donors.

In 1982–1983 came the painful realization that human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) was transmitted via blood transfusions (34). Until then, blood donations were tested only for syphilis serology and hepatitis B virus (HBV) surface antigen. HIV/AIDS mandated a comprehensive overhaul of blood safety which still shapes the regulatory environment of transfusion medicine.

Framework of FDA Regulations

Food and drug regulations (rules) are in Title 21 of the Code of Federal Regulations (CFR) (12). Regulations specific to blood banks are among Parts 600–680, Biologics. General requirements for drug manufacturing, which includes blood products, are in Part 210. General FDA enforcement regulations are in Parts 1–99. The overall principles of current Good Manufacturing Practices (cGMP) are intended to assure that drugs (including blood products) are safe and meet the manufacturers' quality and purity claims (21 CFR 210.1). Rule changes occur infrequently, but numerous blood-related guidances are issued annually. Guidances provide strong recommendations regarding new or updated FDA rules and their enforcement. Proposed and final rules and guidances are published in the *Federal Register*. The final versions are accompanied by useful background information from the FDA on its reasoning and responses to comments.

The Center for Biologics Evaluation and Research (CBER) regulates biological products and has primary responsibility for devices related to biologics such as donor tests, blood bank reagents, blood irradiators, and blood establishment computer systems.

Blood banks and transfusion services are in three categories of FDA oversight (35). (i) Blood centers and other facilities engaging in interstate commerce must be registered with and licensed by the FDA. This includes both establishment licensure and licensure of their main blood components (red blood cells [RBCs], platelets, plasma, cryoprecipitate). (ii) Hospital blood banks which perform blood product manufacturing must be registered. Manufacturing includes autologous and allogeneic blood

collection and component production, blood irradiation, rejuvenation, and washing. Registration is renewed annually. (iii) Transfusion services which only pool platelets or cryoprecipitate or prepare RBCs from whole blood are not required to register, and FDA cedes their routine oversight to CMS under CLIA.

Registered facilities are inspected biennially. FDA's inspection policy guides are available online (36). Inspection observations are provided on FDA Form 483, which includes the agency address to send objections or corrective action plans. Filing a response even if not requested is prudent for future inspections. Serious violations may result in escalating sanctions and even civil or criminal prosecution.

Blood Collection and Component Production

Blood collection facilities are required to provide prospective blood donors written information on eligibility, including risk factors for HIV and hepatitis. Donors are questioned confidentially for infection risk factors and donor safety factors as required by the Donor History Questionnaire (DHQ), which is developed by blood center organizations and approved by the FDA (37).

During the COVID-19 pandemic, several risk factor deferral periods were shortened from 12 months to 3 months because of concern for blood shortages. This includes the most controversial deferral, men who have sex with men (MSM). Beginning in 1983 this was an indefinite deferral for all MSM exposure since 1977; then, in 2015, the deferral was shortened to exposure within the previous year. Advocates argued this singled out gay men unfairly. In 2023, the FDA issued guidelines to screen for individualized risk of recent sexually transmitted disease based on sexual practices, not gender, which will permit many MSM to donate (38).

After prospective donors pass the DHQ, their temperature, blood pressure, and hemoglobin level are checked against acceptable ranges. Donor eligibility must be verified in the blood center's deferral registry. Blood specimens are collected for infectious disease testing and then whole-blood or apheresis collection is performed.

The FDA determines which infectious-disease agents represent risks for transfusion-transmitted infections (21 CFR 610.40) (12). Tests for infectious agents in blood donors must be performed by assays approved for that purpose by CBER. Every donation must be tested for HIV types 1 and 2, HBV, hepatitis C virus (HCV), human T-cell leukemia/lymphoma virus types I and II, and syphilis (39). Through blood guidances, the FDA also recommends donor testing for West Nile virus (WNV) (all donations), *Trypanosoma cruzi* (Chagas disease) (one-time basis), and babesiosis (only in states at risk). Parvovirus B19 testing is recommended for plasma donations being made into plasma-derived blood products.

Thanks to these multiple safety layers in donor screening and testing, the residual risks of classic transfusion-transmitted infections are quite low. Nucleic acid testing shortens the seroconversion windows down to 7 to 9 days for HIV and HCV and 18 to 27 days for HBV, from the time a newly infected donor is infectious until their test turns positive. The residual estimated risks of transfusion transmission per unit are 1 in 1.0 million to 1.5 million for each of these agents (40).

A prominent example of regulatory influence on transfusion practice has been mitigation of bacterial contamination in platelets. Despite earlier measures, septic reactions and fatalities from bacteria in room-temperature-stored platelets were the most common transfusion-transmitted infections. The FDA enacted a guidance in 2019 recommending enhanced bacterial detection, improved culture methods, or pathogen reduction technology (PRT) (41). In PRT, plasma or platelets are treated with agents to inactivate pathogens (42, 43). The FDA-approved PRT for platelets employs a UV-activated psoralen compound which crosslinks nucleic acids. PRT platelets were approved by the FDA in 2014, but not widely used until the FDA guidance for mitigating bacterial sepsis took effect. PRT platelets then rapidly became the most common platelet product in the U.S.

The FDA sets criteria for the content and storage of each blood component to meet desired efficacy and transfusion outcomes. The "package insert" for blood components is the *Circular of Information for the Use of Human Blood and Blood Components*, which summarizes content requirements, indications for use, storage conditions and duration, adverse events, and further processing for each component (44). The circular comprises part of FDA-approved labeling and must be provided to prescribing physicians upon request.

Transfusion Services

The scope of federal regulations for transfusion services focuses on safety, purity, and potency of blood components. RBC compatibility testing is mandated in 21 CFR 606.151, including retesting antibody screens every 3 days in recently transfused or pregnant patients (12).

Electronic crossmatching (e-XM) using the laboratory computer to select RBC units is permitted under specific guidelines for FDA-approved computer systems with either electronic specimen labeling verification or at least two current or historical confirmatory patient specimens (45). If only one non-electronically verified specimen has been received, group O RBCs are given until a second specimen is tested. These measures help prevent mistransfusions based on specimens mislabeled with the wrong patient identification (wrong blood in tube). Wider implementation of e-XM with these precautions has coincided with significant reductions of fatal ABO-incompatible RBC

transfusions in the U.S. (46, 47). Signed documentation of life-threatening emergency from an ordering physician is required when RBCs are issued (even if not transfused) before compatibility testing is completed.

Unlike all other laboratories, CMS CLIA regulations require that the director and technical supervisor of an immunohematology laboratory must be a physician [42 CFR 493.1449(q)] (12). Another unique difference is that in proficiency tests for ABO and RhD typing and cross-matching, the passing grade is 100% (5 of 5 challenges), not 80% (42 CFR 493.859-863) (12). Antibody screening was also changed to 100% in 2023.

Reporting Requirements

Blood collection facilities may discover issues with donor eligibility or product suitability affecting blood components already issued to transfusion services. Approximately 1 in 250 blood components is involved in subsequent notices from blood suppliers (48). Recalls involve products in violation of regulations (21 CFR 7.3) (12). Market withdrawals involve minor violations not subject to legal action. Lookbacks are notices about products previously issued and collected from donors who subsequently tested confirmed-positive (or confirmation cannot be done) for an infectious disease agent. For HIV- and HCV-positive donors, FDA and CMS regulations require that their past donations must be traced and surviving recipients (and next of kin in HIV lookbacks) must be notified and offered testing (21 CFR 610.46-47, 42 CFR 482.27) (12). Suggested management of notices from blood suppliers has been reviewed (48). Blood collection facilities must report recalls to the FDA. All recalls are published weekly in the FDA Enforcement Report (49).

All blood banks and transfusion services must report biological product deviations (BPDs) to the FDA (50). BPDs involve blood products which were distributed but later found to have problems which may have affected their safety, purity, or potency. The FDA publishes an annual summary of BPDs.

When a complication of blood donation or transfusion is confirmed to be fatal (the regulation's wording), the fatality must be reported to the FDA [21CFR 606.170(b)] (12, 51). On average, 35 to 40 transfusion fatalities and three donor fatalities occur each year in the U.S. The leading transfusion causes are transfusion-associated circulatory overload (TACO) and transfusion-related acute lung injury (TRALI).

Cellular Therapies

Federal regulation of the manufacture of hematopoietic progenitor cells (HPCs) has been evolving since 2005. Minimally manipulated bone marrow cells are not considered to be manufactured. For regulated products, the main emphases are safety for the recipient and efficacy for these therapies that are considered to be drugs. FDA rules cover manufacturer registration, donor screening and testing, and cGMPs for tissues (21 CFR 1270-1271) (12). CBER regulates peripheral blood stem cells (PBSCs) and umbilical cord cells (UCCs) from autologous and related donors as tissues. Minimally manipulated PBSCs and UCCs from unrelated donors are regulated as drugs and/or biologics, and must be either licensed or used under an investigational new drug (IND) authorization, as of 2011 for UCCs and 2021 for PBSCs (52). Several U.S. UCC banks have FDA licenses. More complex modalities such as immune effector cells (e.g., chimeric antigen receptor T [CAR-T] cells) and gene therapies must also have FDA preclearance by licensure or IND authorization.

The *Circular of Information for the Use of Cellular Therapy Products*, produced by stakeholder organizations with FDA participation, provides extended labeling information for unlicensed minimally manipulated HPCs, PBSCs, UCCs, and other blood- or marrow-derived cells (53).

Current and Future Regulatory Challenges

Not only safety but also sustainability of the U.S. blood supply is critical for the national healthcare system. Blood component shortages related to the COVID-19 pandemic illustrated vulnerabilities in the complexity of the blood supply chain and prompted reexamination of donor deferral recommendations and the potential return of compensating donors for blood component donations. New types of blood components are undergoing development under regulatory oversight. COVID-19 convalescent plasma went through several complex phases of FDA authorization during its short-lived application (54), and similar passive immune therapy may come back around for future infections. Platelet products are under active development, with investigations of cold-stored platelets for surgery and trauma (55) and reconsideration of whole-blood-derived platelets to meet growing demands (56). The use of group O whole blood for trauma is growing, but manufacturing practices (e.g., anti-A/B titer limits) have not yet been standardized (57). PRT for RBCs is in clinical trials (58, 59), offering the future possibility of universal PRT for all blood components and reforms in traditional approaches to screening and testing for new infectious agents.

Clinical Laboratory Workplace Safety

Laboratory safety is one of the most important responsibilities of laboratory management (60). To ensure there is a safe working environment, laboratory managers and directors should have a basic understanding of applicable Occupational Safety and Health Administration (OSHA) regulations for clinical laboratories.

OSHA was created as a result of the passage of the Williams-Steiger Act of 1970, commonly known as the Occupational Safety and Health Act (61). In keeping with its mission to "save lives, prevent injuries and protect the health of America's workers," OSHA establishes and enforces legally enforceable protective standards. OSHA finalized laboratory safety regulations in 1990 to protect workers from chemical, biological, physical, and other safety hazards. Most of the standards applicable to the clinical laboratory fall under Code of Federal Regulations 29 CFR 1910. More information about OSHA's mission and a link to the Occupational Safety and Health Act of 1970 are available at OSHA (https://www.osha.gov/ [accessed 8 May 2023]).

A complete safety program includes all aspects of laboratory safety, including identification of risks and hazards; comprehensive biohazard, microbiological, chemical, and waste disposal policies and procedures; methods and procedures for training and competency; records maintenance; and accident reporting methods and documentation. Table 2.10 lists components that should be included in a laboratory safety program.

Risk Assessments

Laboratory testing is frequently associated with a high risk of exposure to biological, chemical, and environmental hazards. A risk assessment should be performed prior to the implementation of new test methods or instrumentation. This allows laboratory staff to determine risk of exposure to chemical, biological, and environmental hazards, create safety enhancing procedures, and ensure proper training (62). A thorough risk analysis will identify

Table 2.10 Elements of a laboratory safety program

Maintenance and inspection of the laboratory
Appoint a laboratory safety officer and chemical hygiene officer.
Establish training protocols.
Identify and assess hazard risks.
General safety program
Develop guidelines for personnel responsibility, including prohibiting smoking, eating, drinking, and applying cosmetics in areas where there are biohazards and chemicals; appropriate dress codes; and use of personal electronic devices in laboratory areas.
Provide proper personal protective equipment and describe appropriate use.
Implement effective work practice and engineering controls.
Comply with local and federal regulations for specimen transport within and outside the facility.
Develop hazardous-waste disposal procedures.
Warning signs and labels
Alert employees and visitors to particular hazards such as flammables, combustibles, biohazards, and hazardous chemicals.
Use OSHA-specified signage when applicable.
Fire prevention and emergency management
Develop procedures for fire prevention and control and use of fire prevention equipment.
Establish fire evacuation protocols.
Establish procedures for handling flammable chemicals.
Electrical safety
Include provisions for electrical safety checks of instruments and outlets and proper repair and maintenance.
Compressed gases
Include provisions for proper storage, labeling, transport, maintenance, and pressure regulators and valves of both flammable and nonflammable gases.
Chemical safety
Develop procedures for proper classification of chemicals, material safety data sheets, labels, storage, transportation, personal protective equipment, spills, clean-up procedures, and proper use of hoods.
Personal protective equipment
Establish a chemical hygiene plan that includes OSHA-specified information.
Carcinogens
Develop protocols that include special precautions, proper labeling and disposal, medical exams, storage, and transport.
Microbiological hazards
Establish procedures for blood-borne pathogens (HBV, HIV, and HCV), and other highly infectious pathogens commonly encountered in the clinical laboratory, and specimens and procedures involving highly virulent agents.
Anatomic pathology
Establish procedures for use of special equipment with knives or blades, handling of radioactive specimens for surgical pathology, and autopsy areas.
Occupational health and safety
Establish procedures for reporting and assessing illnesses, injuries, and incidents.
Develop an ergonomics program.

risks, determine the probability of occurrence, and prepare incident prevention plans. Assessment plans should be routinely reevaluated for effectiveness (63).

Chemical Hazards

OSHA standard 29 CFR Part 1910.1200, also known as the Hazard Communication Standard (HAZCOM), was originally published in 1983. Intended to protect workers from hazardous chemicals in the workplace (64), this version of the standard specifically included employees and employers in certain industries. Research laboratories in academic institutions and laboratories in other industries were not included. Following court challenges, OSHA was required to extend the standard to all employees who work with, or are exposed to, chemicals. The final HAZCOM became effective in 1988 (65).

The laboratory community quickly realized that the OSHA standards, designed for industrial-scale operations, were not appropriate for clinical laboratories. As a result of comments and concerns from the laboratory community, an effort to craft a separate regulation for laboratories began. The result was OSHA Standard 29 CFR Part 1910.1450, "Occupational exposure to hazardous chemicals in laboratories," also known as the laboratory standard, which became effective in 1990 (12, 66). In most cases laboratories are held to the laboratory standard rather than the HAZCOM standard (65).

There are key differences between the laboratory and HAZCOM standards. The laboratory standard adds requirements for development of a chemical hygiene plan, appointment of a chemical hygiene officer, and a requirement that standard operating procedures be available (65). The OSHA laboratory standard is not intended to supersede *all* OSHA standards. OSHA rules and standards on areas not mentioned in the laboratory standard are still in effect. (i) Plan ahead, (ii) minimize exposure, (iii) don't underestimate risks, and (iv) be prepared for accidents are the four basic principles that should underlie all work with chemicals (66). Table 2.11 lists the elements of a chemical hygiene plan. Safety policies and procedures should address safe handling, storage, and disposal of chemicals, inventory control, proper use of personal protective equipment (PPE), equipment maintenance, and emergency response (67) (see Table 2.12).

Table 2.11 Elements of a chemical hygiene plan[a]

Standard operating procedures
Chemical procurement, distribution, and storage
Environmental monitoring
Housekeeping, maintenance, and inspections
Medical program
Protective apparel and equipment
Records
Signs and labels
Spills and accidents
Information and training program
Waste disposal program

[a] See 29 CFR 1910.1450 (12).

Table 2.12 Safe handling of chemicals[a]

Review the safety data sheet.
Plan ahead and perform a risk assessment.
Observe general safety procedures.
Wear eye protection or face protection.
Use the proper gloves.
Purchase minimum quantities of chemicals.
Properly label and store chemicals.
Leave exits and emergency equipment unobstructed.
Know emergency procedures and use of emergency equipment.

[a] See reference 139.

Biological Hazards

Over time, and with increasing knowledge, laboratories have seen changes in the precautions used in handling laboratory specimens. Laboratories have moved from procedures that employed special handling of known or suspected infectious specimens to those requiring the handling of virtually all human specimens as if they were infectious. Over the years, handling of human specimens has progressed from labeling known infectious specimens as "blood and body fluid precautions" to following the recommendations from the CDC and advisories from HHS and the Department of Labor on ways to protect healthcare workers from occupational exposure, warnings from OSHA that healthcare institutions not following the guidelines are subject to fines and prosecution (68), and federal requirements as promulgated in the OSHA Bloodborne Pathogen Standard.

OSHA's Bloodborne Pathogen Standard became effective in 1992 (69, 70). The standard protects employees who work with blood, body fluids, or other potentially infectious materials by requiring that employers provide certain safeguards. Recognizing that carriers of blood-borne pathogens are not always identified and that contaminated materials are not consistently labeled, the standard fundamentally changed previous practices. Standard Precautions, the practice of assuming that all human blood and body fluid specimens are potentially infectious, is the basis of the standard (29 CFR 1910.1030) (12). Requirements of the plan are summarized in Table 2.13.

OSHA provides a compliance directive, CPL 02-02-069, "Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens" (71). The directive provides clarification to OSHA inspectors and sets policy for use in conducting inspections to enforce the Occupational Bloodborne Pathogen Standard. Clarifications are provided in Table 2.14.

Table 2.13 Blood-borne pathogen exposure control plan requirements

Determination of employee exposure to blood and other potentially infectious materials
Implementation of methods of exposure control, including:
Universal precautions
Engineering and work practice controls—including sharps management, laboratory hygiene, and waste disposal
Personal protective equipment
Housekeeping
Policy for hepatitis B virus (HBV) vaccinations
Procedure for postexposure examination and follow-up
Communication of hazards to employees and training
Record keeping
Procedure for evaluating exposure incidents

[a] See http://www.osha.gov/Publications/osha3186.pdf (accessed 10 May 2023) (140).

Other Infectious Hazards

Laboratory staff may potentially be exposed to other infectious diseases not found in blood or body fluids. The primary routes of transmission are contact, droplet, and airborne pathways. Workers in microbiology laboratories may be at increased risk of infection by contact exposure, such as to methicillin-resistant *Staphylococcus aureus*, which may be found on work surfaces. Other pathogenic organisms may become airborne, such as *Bordetella pertussis* and *Mycobacterium tuberculosis*. Additional OSHA regulations, the Personal Protective Equipment (PPE) standard (29 CFR 1910.132) (12), Respiratory Protection standard (29 CFR 1910.134) (12), and OSHA's TB compliance directive (70), include provisions for infection control methods to further reduce exposure. Implementation of additional PPE, such as N95 masks, and/or utilization of biological safety cabinets protect laboratorians from these additional risks (72).

In March 2020, laboratories across the U.S. were on the forefront of an unprecedented response to the COVID-19 pandemic. Processes to collect, handle, and test record numbers of specimens for SARS-CoV-2 were put into place. Laboratory managers also implemented safety precautions to maintain a healthy and safe working environment. With SARS-CoV-2 delta variant infections rapidly rising, OSHA released on January 29, 2021, an Emergency Temporary Standard to protect workers from the dangers of COVID-19 while working in healthcare settings (73). This guidance addressed multiple susceptible workplace factors and encouraged a workplace hazard assessment. Assessment elements included availability and use of appropriate PPE, disinfection procedures, physical distancing processes, patient medical screening and management, ventilation, and vaccination. Processes for training, record keeping, and reporting of COVID-19 cases were all required under the temporary standard. Guidance was

Table 2.14 Clarifications provided in enforcement procedures for occupational exposure to blood-borne pathogens

All employees (part-time, temporary, and per diem) are covered. OSHA jurisdiction does not include students.
An exposure control plan, either a "cohesive entity" or a guiding document, must be provided stating what separate policies make up the plan.
The plan must be updated at least annually. Updates should include changes in technology, changed or new tasks that present exposure, and changed or new job classifications presenting exposure. The plan must include provisions for reviewing exposures and the circumstances under which they occurred.
Because hepatitis B virus (HBV) is easily transmitted by environmental contamination, contaminated work surfaces must be cleaned with an "appropriate disinfectant." Dilute bleach is an effective disinfectant. A 1:10 dilution of stock household bleach (0.5% sodium hypochlorite) is considered to be effective in the time it takes to dry. For commercial products, users must follow the instructions. Gross contamination must be cleaned first with a soap and water solution to ensure a disinfectant's effectiveness. Other U.S. Environmental Protection Agency–registered products may be obtained from the online information at https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants (accessed 8 May 2023).
Sharps containers must not be overfilled. OSHA notes that the EPINet Sharps Injury and Blood and Body Fluid Data Reports, including data from 41 hospitals in 2021, found that 2.4% of injuries occurred during disposal into a sharps container (https://internationalsafetycenter.org/exposure-reports/) (accessed 8 May 2023).
Potable eyewash facilities are not acceptable unless they contain at least a 15-minute supply of free-flowing water and both hands are free to hold eyelids open.
OSHA notes changes in treatment of HBV. Employers are required to use the most current CDC guidelines. (Current guidelines are located on the Centers for Disease Control and Prevention website at https://www.cdc.gov/hepatitis/hbv/index.htm [accessed 8 May 2023].)
Exposure documentation, to be useful in creating recommendations to prevent future accidents, must contain useful information including the circumstances of the exposure, the route of exposure, engineering and work practices in use, what device was in use, and personal protective equipment in use at the time.
Training must include description of blood-borne pathogens in addition to HIV and HBV. OSHA notes that hepatitis C virus is now the "most common chronic bloodborne infection in the United States." Training need not include a discussion of the transmission and symptoms of less common diseases.
Training may not be accomplished solely using a film or video. Trainees must have the opportunity to ask questions of the trainer.
Accurate training records must be maintained for 3 years. Such records should include the names and job titles of the attendees.

updated on June 10, 2021, to include recommendations for mask and testing process for fully vaccinated individuals (74, 75). Although laboratory processes have been streamlined and become routine, proper protection for staff members remains a priority.

Transportation of Clinical Specimens

Shippers of hazardous materials not only are required to follow the regulations but must have documented training every 2 years. The individual signing the shipping documents as the "certified shipper" assumes responsibility for the complete shipping process and, according to law, is the one person deemed fully responsible for the condition of the specimen packaging. The certified shipper is responsible for determining several aspects of packaging: determining if the specimen is a regulated substance, knowing the regulations governing that substance and the appropriate packaging to use, accurately completing all required documentation and shipping papers, correctly marking and labeling the package, and notifying the recipient of the shipment. Fines for improper shipping or lack of training are substantial. The Federal Aviation Administration employs lawyers and cargo security specialists to conduct preventive measures ensuring safety.

Physical Hazards

Sharps. As a result of the efforts of healthcare worker advocates, the Federal Needlestick Safety and Prevention Act (HR 5178) (76) was signed into law in 2000. The bill mandated that OSHA revise and enforce the existing Bloodborne Pathogen Standard. Specifically, the law required that OSHA revise the Bloodborne Pathogen Standard by strengthening employer requirements for "identification, evaluation, documentation and use of safety engineered sharp devices"(77, 78). Highlights of the revised standard are that employers must maintain a sharps injury log that contains, at a minimum, the type and brand of device involved, where the incident occurred, and a description of the incident; exposure control plans must be reviewed annually and include documentation that consideration has been made of available safety devices reflective of technological advances; and input must be solicited from front-line employees for the "identification, evaluation and selection of effective engineering controls, including safer medical devices." Other revisions include amendment of the term "engineering controls" and the addition of definitions for "needleless" systems and "sharps with engineered sharps injury protection" (78).

Ergonomics. Work-related musculoskeletal disorders are most often caused by repetitive tasks, poor posture, and muscle strain. The 2020 Bureau of Labor Statistics reports that 30% of all workplace injuries are due to musculoskeletal disorders, with an estimated 12 days away from work for every injury (79). In 1990 OSHA created the Office of Ergonomics Support. The following decade saw proposed rulemaking and publication of a proposed ergonomics standard, culminating in November 2000 with President Clinton signing the first ergonomics rule. The OSHA ergonomics standard went into effect in January 2001 (80). Court challenges and politics resulted in Congress repealing the standard in March 2001, thus marking the first time a rule was successfully overturned through use of the Congressional Review Act (81).

OSHA's interest in ergonomics was not diminished by the congressional action. In 2002, OSHA announced a "Comprehensive Plan to Reduce Ergonomic Injuries." This comprehensive plan calls for guidelines targeted at specific industries, combined with enforcement, assistance with compliance, Hispanic outreach, and ergonomics research (82). Since 2002, OSHA has published several industry and task-specific ergonomic guides to help employers prevent and reduce musculoskeletal disorders in the workplace.

Although the OSHA ergonomics standard was repealed, employers should continue to be concerned about ergonomic injuries. Not only is OSHA likely to implement ergonomic reviews under its "general duty" clause, but with an estimated 2.7 million lost days from work in 2020, employers cannot afford to ignore ergonomic issues (79).

Ergonomics has been defined as "the science of fitting jobs to people" (80). Some laboratory tasks posing a particular risk of ergonomic injury include conventional microtomy, microscope use, biological safety cabinet and hood use, manual pipetting, phlebotomy, sitting for long periods, and long periods of computer entry (83). By studying the amount of time spent at a particular task, how long people are in the same position, repetitive motion, and awkward positions, among other factors, managers can work to reduce ergonomic injuries. (Some ergonomic guidelines are listed in Table 2.15.)

Latex. Latex allergy has become a major healthcare concern. Latex hypersensitivities and allergies increased rapidly in the healthcare industry during the 1980s and 1990s. This was most likely attributable to the increased use of latex gloves following implementation of OHSA's Bloodborne Pathogen Standard requiring employees to use gloves when working with blood and body fluids. In 2008 the FDA published an industry guidance on medical gloves that includes glove powder limitations and recommendations for product labeling (84). Latex gloves have widely been replaced with nitrile, polyethylene, or vinyl products; however, thousands of commercial products containing latex proteins are still being produced, keeping

Table 2.15 Computer workstation and general ergonomic guidelines (not a comprehensive list)[a]

Hold head, neck, and body upright and facing forward.
Forearms, wrists, hands, and thighs should be parallel to the floor.
Feet should rest flat on the floor or on a footrest.
Top of the monitor screen should be at or below eye level and directly in front of the employee.
The mouse or trackball should be next to the keyboard and be easy to activate.
Wrists and hands should not rest on sharp or hard edges. Wrist rests, if used, should be padded, with no sharp or square edges.
Chairs should provide lumbar support and have armrests and a seat size appropriate to the employee.
Chair seats should be cushioned; the front edge of the seat should not be sharp or push against the back of the employee's lower legs or knees.
Avoid repetitive motions.
Limit microscope use to a total of 5 hours a day, preferably spread over the day.
Position the microscope so the operator sits as straight as possible.
Use armrests to support the forearms while using adjustment knobs.
Use an antifatigue mat if long periods of standing are required.
Take frequent short breaks to stretch.

[a] OSHA provides an "e-tool" on hospital ergonomics, with specifics for laboratories, on its website at http://www.osha.gov/SLTC/etools/hospital/index.html (accessed 8 May 2023). The CDC provides additional information on ergonomics at http://www.cdc.gov/niosh/topics/ergonomics/ (accessed 8 May 2023).

latex allergy a concern among healthcare workers. In addition, supply chain issues during the COVID-19 pandemic during 2020–2021 caused latex glove products to be placed back into the laboratory environment. Workers exposed to latex may exhibit several types of reactions: irritant contact dermatitis or allergic contact dermatitis which cause skin irritations and reactions. More severe reactions may include respiratory symptoms such as asthma and occasionally anaphylaxis (85).

The National Institute for Occupational Safety and Health (NIOSH) recommends that employers adopt policies to protect workers from undue latex exposure in the workplace. Some strategies to consider include providing nonlatex gloves where appropriate (minimal contact with infectious materials), using reduced-protein, powder-free gloves when latex gloves are used, ensuring good housekeeping practices to minimize latex-containing dust, educating workers about latex allergy, periodically screening high-risk workers for latex allergy, and evaluating the program whenever a worker is diagnosed with latex allergy (86).

Additional Safety Regulatory Resources

American National Standards Institute (ANSI). Founded in 1918, ANSI comprises over 1,000 companies and organizations, both public and private. A private, nonprofit organization, ANSI "administers and coordinates the U.S. voluntary standardization and conformity assessment systems" (American National Standards Institute, available at http://www.ansi.org [accessed 8 May 2023]). ANSI publishes safety standards developed by its accredited standards committees and publishes specifications for safety equipment including eyewash, emergency shower facilities, and protective eye equipment (safety glasses and goggles). ANSI, through its membership in the International Organization for Standardization (ISO), coordinates internationally adopted safety standards.

National Institute for Occupational Safety and Health (NIOSH). In addition to creating OSHA, the Occupational Safety and Health Act of 1970 created NIOSH. NIOSH is an agency of HHS and functions as a research agency charged with conducting research, providing technical assistance, and recommending standards adoption. (More information about NIOSH is available at https://www.cdc.gov/niosh/index.htm [accessed 8 May 2023].) NIOSH recommends safety hazard controls, is a leader in assessment and documentation of hazard control technology, and conducts classes throughout the country, but it possesses no enforcement authority.

ANSI and NIOSH work closely with OSHA in setting laboratory standards. This arrangement recognizes OSHA's authority in the development and enforcement of health and safety standards while at the same time recognizing the important role that national-consensus-standard-producing organizations play in the development of occupational health and safety standards. The memorandum states that ANSI will continue working to develop national consensus standards for OSHA's use and that OSHA will cooperate with ANSI and assist in its mission. The agreement calls for close cooperation in the areas of technical support, consultation in planning of standards development activities, sharing of reports, and other areas. This cooperative effort is intended to assist OSHA in carrying out its responsibilities through the use of ANSI's technical support and resources.

Clinical and Laboratory Standards Institute (CLSI). The CLSI (formerly the National Committee for Clinical Laboratory Standards or NCCLS) is a voluntary global organization that develops consensus standards and guidelines for clinical laboratories and other audiences. Over 2,000 member organizations drawn from government, industry, and the professions propose, review, comment on, and approve standards and guidelines (68).

Centers for Disease Control and Prevention (CDC). The CDC is an agency of the federal government and tracks, monitors, and researches disease. Of interest to laboratories is the CDC publication *Morbidity and*

Mortality Weekly Report. This weekly report provides information on blood-borne pathogens and infectious waste disposal recommendations, among other topics. Guidelines published by the CDC are published in the *Federal Register* and may be incorporated into OSHA standards. The blood-borne pathogen exposure control guidelines set forth by CDC became the OSHA Bloodborne Pathogen Standard published as 29 CFR 1910.1030 (12).

Department of Transportation (DOT) and International Air Transport Association (IATA). DOT is responsible for coordinating the safety program for shipment of hazardous goods within the United States. Of particular interest to laboratories, biohazardous materials, infectious materials, and dry ice are classified as hazardous goods (Table 2.16). The Office of Hazardous Materials Safety, which is located in the Research and Special Programs Administration Office of the DOT, develops and administers the Hazardous Materials Regulations (HMRs), which can be found in the Code of Federal Regulations (49 CFR parts 100–185) (12).

Both the DOT's HMRs and the IATA regulate shipment of hazardous goods sent by air. Air carriers worldwide have a major interest in ensuring the safe shipment of dangerous goods. The IATA functions as their international trade association. The DOT and IATA both base their regulations on the recommendations of the United Nations Committee of Experts (UNCOE). Although both organizations derive their regulations from the recommendations of the UNCOE, IATA's adds additional restrictions. The IATA regulations are updated frequently and published annually in the IATA Dangerous Goods Regulations (https://www.iata.org/en/publications/dgr/ [accessed 8 May 2023]). Laboratories adhering to the IATA regulations for shipping infectious or biohazardous materials can be assured of also complying with DOT's HMRs (87).

Table 2.16 Hazard classes and definitions[a]

Class	Definition
1	Explosives
2	Gases (flammable, nonflammable, and poison)
3	Flammable and combustible liquids
4	Flammable solids, spontaneously combustible material, dangerous when wet
5	Oxidizers, organic peroxide
6	Poisonous materials, infectious substances (6.2)
7	Radioactive materials
8	Corrosive materials
9	Miscellaneous hazardous materials (includes dry ice)
Other regulated materials	

[a] See 49 CFR 172.101 (12).

Overview of Laboratory Reimbursement Regulation

U.S. Healthcare

Healthcare is one of the largest segments of the U.S. economy. In 2021 the United States spent $4.3 trillion on healthcare, 18% of the gross domestic product (88, 89). Of the total healthcare budget, 31% was for hospital care (31%) and 20% for physicians and clinical services (Table 2.17) (90). Eight percent of all healthcare dollars went to government and private insurance administration, reflecting the complexity of the reimbursement processes outlined below. CMS projected that during 2021–2030, U.S. healthcare spending will rise around 5.1% annually (91).

In 2021, Medicare, Medicaid, and other government programs (Children's Health Insurance Program or CHIP, Department of Veterans Affairs, Department of Defense) paid for 36% of U.S. healthcare, private insurance covered 28%, and 10% was paid by the public out of pocket (Table 2.17). Government and private programs for public health, school and workplace health, the Indian Health Service, and others accounted for 16%. By overall sponsor, 49% of healthcare dollars came from governments (federal, 34%, and state and local, 15%) and 50% came from the private sector: households (27%), businesses (17%), and others (7%) (90). The Affordable Care Act of 2010 expanded eligibility for Medicaid (subject to state

Table 2.17 U.S. healthcare economy[a]

Funders (%)	Payors (%)	Payees (%)
U.S. 36%	Private insurance 28%	Hospital care 31%
Households 26%	Medicare 20%	Physicians and clinical services 20%
Private businesses 17%	Medicaid and CHIP 17%	Home health, residential and personal care 8%
State/local governments 14%	VA and Dept of Defense 3%	Nursing care 5%
Other private 7%	Government public health 5%	Prescription drugs 8%
	Out of pocket 9%	Dental services 3%
	Other programs 12%	Other professional services 3%
	Investment 5%	Public health 5%
		Non-durable products 2%
		Durable medical equipment 1%
		Investment 5%
		Government administration and net cost health insurance 8%

[a] CHIP, Children's Health Insurance Program; VA, Department of Veterans Affairs (references 88 to 90).

participation) and subsidized private insurance for low-income persons (92). However, in 2021 9.8% of persons under 65 did not have health insurance (93).

Medicare provides health insurance for persons over 65 or with long-term disability or end-stage renal disease. Medicaid is a joint federal/state program funding medical services for persons with low incomes. Low-income persons on Medicare may receive additional coordinated benefits from Medicaid. CHIP is a federal program extending health coverage to another cohort of low-income children with income above the threshold for Medicaid. Beyond certain federally mandated Medicaid coverage groups, each state establishes its own eligibility criteria for Medicaid and CHIP (91).

Among the entire U.S. population—331.9 million in the 2020 census (93)—63.9 million (19.3%) were on Medicare in 2021 and 83.5 million (25.2%) were on Medicaid (94). CHIP covered 7.1 million children (2.1% of the total population) and 9.6% of children under 18 (93). These three groups overlap as noted above.

Medicare

Medicare has Parts A through D (91). Part A includes inpatient hospital care, skilled-nursing facilities, home health agencies, and hospices. Part A is provided at no cost to beneficiaries. The other parts are voluntary. Part B coverage includes services from physicians and other Medicare-approved providers, outpatient clinics and therapies, ambulatory surgery, laboratory tests, radiology, organ transplants, and drugs and biologicals not self-administered, including blood transfusions. Part D is for prescription drugs. Parts B and D premiums are income-adjusted. Part C, Medicare Advantage (MA) plans, are purchased from private insurers as extensions of regular Medicare Parts A, B, and sometimes D. MA plans have additional benefits and/or reductions of Medicare cost sharing for copayments and deductibles.

Pathology and Laboratory Services in Medicare

Pathology services and laboratory testing are a significant segment of Medicare services. In 2020, 81% of 32.1 million Medicare beneficiaries receiving care had diagnostic laboratory testing. The 278.1 million tests performed comprised 24.2% of all individual services (95). Nineteen percent of these beneficiaries received pathologist services. Nearly 10% of Medicare payments were for laboratory testing. Pathologists provided medical oversight of most of these tests and received 0.9% of Medicare payments for pathologist services.

Claims Processing

Fee-for-service claims for Medicare Parts A and B, home health, hospices, and durable medical equipment are processed by Medicare Administrative Contractors (MACs) serving contiguous groups of states (96).

MACs are private insurers contracted by CMS. For Parts A and B, 12 regions are served by eight MAC companies; four companies have two regions each. The other claims categories are subdivided into four regions. MACs also oversee the activities of multiple subcontractors who process data, field questions, coordinate other benefits, and audit claims (97). Coverage determinations and coding for diagnoses and services are discussed elsewhere in detail (chapters 31 through 36 of this volume).

Reimbursement for Physician Services

Medicare's Physician Fee Schedule itemizes how much Medicare pays for each physician service. Physician time and effort needed to render a service, plus practice and malpractice expenses, are translated into relative value units (RVU) for that service, which are in turn converted to dollars (1). One basic RVU in 2021 was paid $34.89 (98).

The College of American Pathologists (CAP) compiles annually updated tables of pathology-related professional services, CPT codes, and their payments. In 2022, generic pathology clinical consultations were expanded from two to four options (80503 to 80506 code range) based on the total time or level of medical decision making needed to provide the service (99).

Most physicians are participating providers in Medicare. They receive 80% of the fee schedule from Medicare for services and bill the beneficiary for their 20% copayment (100). Participating providers are not allowed to bill Medicare beneficiaries an extra amount for services covered by Medicare and are, thus, not permitted to charge beneficiaries more than the total Medicare fee schedule. Nonparticipating providers are paid by the patient and the patient is reimbursed from Medicare. These providers are not allowed to bill the patient more than 15% above the Medicare fee schedule.

Medicare is in the process of building quality and value into the traditional fee-for-service model of professional reimbursement. The Medicare Access and CHIP Reauthorization Act (MACRA) was passed in 2015 and slated to be be fully phased in by 2025. Under MACRA, reimbursements based on RVUs could be adjusted up or down as much as 9% based on compliance rankings for quality performance metrics 2 to 3 years previously (101–103).

The overall payment system under MACRA is designated the Quality Payment Program (104). Within the QPP there are two pathways: (i) Merit-based Incentive Payment System (MIPS), the default pathway, and (ii) Advanced Alternative Payment Methods (APM) in a limited number of organizations and networks. For pathologists who do not see patients directly, the general principles of MIPS are to perform designated quality practices (85% of MIPS score) and to participate in designated improvement activities (15%) (105, 106).

Recent approved quality practices include biopsy turnaround times and inclusion of recommended morphological or molecular evaluations in pathology reports of designated cancers (107). Areas for approved improvement activities include care coordination, patient safety and practice assessment, expanded practice access, and emergency response and preparedness. MIPS metrics change from year to year as new ones are introduced and some are phased out by CMS due to uniformly high compliance rates. Pathologists may participate in MIPS individually or as part of a group.

APMs are used in a limited number of healthcare programs approved by CMS as models or demonstrations of service delivery innovations. These programs are organized by geographical location, disease, and/or organization type, such as accountable care organizations.

Laboratory Test Reimbursement

The Clinical Laboratory Fee Schedule (CLFS) sets forth how much Medicare Part B pays for each test. Over 1,800 tests are listed (108). Tests on the CLFS are reimbursed only for technical work, not for pathologist interpretation. Eleven test panels are approved by CMS. Tests ordered as a panel must all be run and are reimbursed with one bundled payment, less than the sum of the parts if run separately. Payments for new tests are established by comparison with similar tests (crosswalking), or when no comparison is available, initially by estimates from charges and resources needed (gap-filling) (109).

The Protecting Access to Medicare Act (PAMA) was enacted in 2014 and became effective in 2018, but its full implementation was delayed multiple times by CMS and Congress (109, 110). One part of PAMA is directed toward lowering Medicare payments per test in the CLFS through collecting data on payments laboratories receive from private payors. Initially CLFS payments were adjusted to a weighted median of private payor rates. Planned reductions from those levels were postponed during the COVID-19 pandemic and continued to be delayed. Per PAMA, the private-sector payment survey is to be repeated on a 3-year cycle (108).

Another provision of PAMA eliminated previous bundled discounts for 23 automated chemistry tests when they were billed on the same day. The HHS Office of Inspector General (OIG) reported that although payments per test were often lowered by PAMA, the net effect of eliminating the automated chemistry discounts and paying the full fee per test contributed to increases in total laboratory payments in 2018 (111). The OIG recommended reinstating the bundling discounts, but CMS has not acted on this.

PAMA simplified 57 local laboratory test fee schedules across the MACs into one national fee schedule. This created a one-time rise in total payments in 2018 for some common tests.

Patient Privacy: HIPAA and Related Regulations

HIPAA Introduction

The Health Insurance Portability and Accountability Act (HIPAA) signed in 1996 by President Bill Clinton had three main purposes: to improve the efficiency of healthcare delivery and health information, to address constraints to healthcare access, and to create a set of standards for transmission of health information records. HIPAA protects healthcare coverage for workers and families when they change or lose employment or have preexisting conditions; establishes standards for electronic healthcare transactions; and protects privacy and security of healthcare data. Several rules and acts were subsequently passed throughout the early 2000s for specific issues not addressed within the original 1996 Act and to ensure continuous improvement surrounding advancements in electronic health records.

Protected Health Information

Protected health information (PHI) is defined as individually identifiable health information that is used, stored, maintained, or transmitted in any form or medium. Health information includes 18 patient demographic identifiers that provide a reasonable basis to believe they will identify an individual. Examples include Social Security number, driver's license number, street address, email address, photographic image, and finger or voice print. Electronic PHI (ePHI) includes health information that is specifically used, stored, maintained, or transmitted electronically, including via personal computers, external storage devices, and smartphones. Transmission methods include wi-fi, Ethernet, modem, digital subscriber line (DSL), or cable network connections to send email or perform file transfers.

Some health-related information used for research studies is not included in PHI. Examples include test results or data that are not entered into the medical record or used for treatment, information that is not associated with a healthcare service event, or a set of results that is not affiliated with PHI, such as a set of vital signs.

Patient Informed Rights

Hospitals and healthcare facilities must inform patients of their rights prior to giving care, must have a grievance process, and must identify a representative for patients to contact. Patients maintain the right to participate in the development of a care plan with their provider and to be adequately informed to make decisions regarding their care.

Consent and Authorization

Healthcare providers may not use or disclose a patient's health information, either verbally, written, or electronically via fax or email, in the course of treatment or billing,

without prior signed consent. Consent allows the use and disclosure of PHI by the Covered Entity seeking payment, but not by other persons. Consent forms are not needed when the Covered Entity has an indirect treatment relationship or is providing care to an inmate.

Use and disclosure of PHI for purposes other than treatment, payment, and healthcare operation requires an authorization specific to the purpose and must contain key core elements as cited in the final rule (112, 113). Authorizations are required for preemployment physicals and determination, life insurance, psychotherapy notes, and clinical trials or research and are more detailed than consent forms.

Privacy Rule

Enacted in 2003, the main goal of the Privacy Rule is to set limits to how and when PHI can be used and disclosed, while still allowing for efficient stream of health information to healthcare entities for effective treatment of the patient. The Rule applies to all Covered Entities: healthcare plans, healthcare clearinghouses, and healthcare providers. Business Associates were also included in 2013 as part of a revised rule for the Health Information Technology for Economic and Clinical Health (HITECH) Act originally passed in 2009 (114).

The HIPAA Privacy Rule applies to all Covered Entities, which include:

- *Health Plans*: individual or group plans that provide or pay the cost of medical care, including health insurance companies, managed-care organizations, insured or self-insured employee health plans, and federally funded health plans.
- *Healthcare Clearinghouses*: public or private entities such as billing agencies, repricing companies, and community health information network systems that convert health information from nonstandard formats into HIPAA standard formats or vice versa.
- *Healthcare Providers*: including institutions, professionals, and medical suppliers that bill the Medicare program or receive payment for health services rendered and that transmit individually identifiable health information (IIHI) electronically, as defined by the HIPAA standard transaction.
- *Business Associate*: a person or organization that acts on behalf of the Covered Entity to perform functions that involve PHI. There must be a Business Associate Agreement (BAA) between the Covered Entity and the Business Associate to ensure safeguard to PHI. Sample Business Agreement contract provisions can be found on the HHS website (https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html [accessed 8 May 2023]).

Security Rule

The Security Rule sets minimum standards for Covered Entities to safeguard PHI and ePHI. Procedures must be implemented to ensure that employees within a Covered Entity or Business Associate who can access, create, alter, or transfer ePHI do so with integrity and confidentiality. Technical and physical safeguards must be put into place to protect healthcare information. Examples include shredding documents containing PHI, optimal workstation design to protect visual access to PHI, encryption of PHI that is sent outside the company's firewall, and development of programs that protect against anticipated threats to security of PHI. Including a Security and Privacy Officer on staff to perform security risk assessments and regular audits adds an additional layer of protection for healthcare entities (115).

HITECH and Omnibus Rule

As part of a stimulus package developed in 2009, goals for the HITECH Act were to incentivize the implementation of electronic health records within healthcare organizations. HITECH also increased enforcement and penalties for privacy and security violations (116, 117). The HIPAA Omnibus Rule went into effect on March 26, 2013 to further protect patient health information in an increasingly digital world. This rule merged HITECH provisions with HIPAA and further addressed privacy and security issues. Two specific revisions directly impacted clinical laboratories (118):

- Broadened the definition of Business Associates and expanded the privacy and security rules; Business Associates were now directly liable for any breach in PHI.
- Allowed patients to have easier access to their protected health information; laboratories must produce records of results within 30 days in the format (including electronic) requested by the patient.

Breach Notification Rule

The Breach Notification Rule mandates that Covered Entities and Business Associates notify the patient and HHS of any breach in secured patient health information within 60 days of the discovery of the breach. Notification should include a description of the breach, the type of information disclosed, steps that individuals should take to protect themselves from harm, and steps the Covered Entities and Business Associates are taking to prevent future breach events (119).

Enforcement Rule

Privacy and security rule enforcement lies with the HHS Office of Civil Rights (OCR). Enforcement activities apply to all Covered Entities and include investigation of complaints, periodic compliance reviews, and educational outreach activities. Complaints may be made by any person,

not just the person who is the subject of a PHI breach. Investigation may involve the Department of Justice and includes a determination whether noncompliance is criminal or civil in nature. Common causes of noncompliance include failing to secure or encrypt data, theft of electronic devices, improper disposal of records, lack of proper associate agreements, lack of employee training, and employee misconduct (120). There may be substantial consequences for individuals and Covered Entities involved with HIPAA noncompliance. A tiered criminal and civil penalty system was implemented under the American Recovery and Reinvestment Act of 2009. Criminal penalties are outlined in Table 2.18; civil penalties are outlined in Table 2.19.

Current Topics in HIPAA Compliance

COVID-19. The OCR issued new changes to HIPAA regulations in 2020 and 2021 in response to the COVID-19 pandemic for the following topics:

- The Coronavirus Aid Relief and Economic Security (CARES) Act of 2020 ensured healthcare for all Americans during the COVID-19 pandemic. The OCR issued guidance for the use of audio-only and electronic telehealth and approved the use of virtual platforms to conduct health assessments. The guidance also allowed participation in community-based testing sites for the collection of specimens for COVID-19 (121).

Table 2.18 Criminal HIPAA penalties[a]

Tier 1	Up to $50,000 and 1 year in prison for knowingly obtaining or disclosing PHI
Tier 2	Up to $100,000 and 5 years in prison when the crime is committed under false pretenses
Tier 3	Up to $250,000 and 10 years in prison if there is intent to sell, transfer, or use PHI for personal gain or malicious harm

[a] 42 USC 1320d-6. PHI, protected health information.

Table 2.19 Tiered penalty system for civil HIPAA violations[a]

Tier	Violation	Penalty
1	Individual unaware of the HIPAA violation	$100–$50,000 per violation Maximum $25,000 for repeat violations
2	HIPAA violation was due to reasonable cause and not willful neglect	$1,000–$50,000 per violation Maximum $100,000 for repeat violations
3	HIPAA violation was due to willful neglect but the violation was corrected within 30 days of discovery	$10,000–$50,000 per violation Maximum $250,000 for repeat violations
4	HIPAA violation was due to willful neglect with no effort made to correct the violation	$50,000 per violation Maximum $1.5 million for repeat violations

[a] Each tier carries a maximum of $1.5 million per year. 45 CFR 160.404 (12).

- As part of the CARES Act, SAMHSA 42 CFR Part 2 was revised to provide better facilitation of healthcare coordination for those receiving treatment for substance abuse disorders. Fundamentals of patient privacy remained unchanged (122).

Gender-affirming care. In March 2022, HHS issued the Guidance of Gender Affirming Care, Civil Rights and Patient Privacy Notice, which reinforced federal civil rights laws for transgender and gender-nonconforming individuals seeking healthcare (although a federal court put a hold on the guidance in October 2022) (123). With the increasing importance of recognizing the complexities in medical care for gender-nonconforming and gender-fluid individuals, medical professionals should take into consideration the patients' gender assigned at birth and their gender identity. Medical and surgical interventions during gender reassignment can lead to difficulties with interpretation of laboratory results and pose difficulties with ordering gender-specific testing (e.g., Pap smear for a transgender male) (124). Simultaneous availability of both male and female reference ranges may be necessary to correctly interpret certain laboratory results. In addition, attention should also be paid to language within pathology reports. Patient access to laboratory results is increasingly available through healthcare portals, and therefore, the use of gender-free descriptions and terminology is important and best serves this patient population (125).

Proposed changes. With the advancement of technology and changes in work practices, a final rule on several proposed HIPAA changes was expected in 2022. As of May 2023, an effective date remains pending. Most of these proposed changes address patient rights of access to their PHI as outlined below (126):

- Permit patients to view their PHI in person; allow pictures and note taking.
- Patient requests for copies of PHI must be delivered in 15 days instead of 30 days.
- Provide a fee schedule for costs associated with requests for PHI copies.
- Ease Covered Entities' requirements for patients to verify their identity.
- Revisions to the maximum penalties for HIPAA violations.

Summary of Laboratory Responsibilities

To ensure compliance with HIPAA laws, laboratories have a responsibility to establish privacy and security policies and procedures and to ensure that laboratory information systems have hardware and software data security systems in place (127). Laboratory management must implement

Business Associate Agreements with all outside entities providing services to the laboratory that may involve PHI (e.g., couriers, accreditation agencies, referral laboratories, etc.). Robust training materials must be developed to educate employees about HIPAA and associated compliance methods. Training should be completed on an annual basis and records maintained. A notification process should be developed for any suspected or known breach of secured PHI. Laboratories should employ a Privacy and Security Officer to conduct periodic audits, investigate any complaints, and develop methods of improvement for any nonconformances.

SUMMARY

In laboratory medicine, regulations for laboratories and blood banks are meant to protect the public, promote quality healthcare, ensure patient privacy, and see that tax dollars for healthcare are spent appropriately. Workplace safety rules help protect laboratory personnel. Effective leadership in clinical laboratories includes compliance with current regulations and adaptation to new requirements in the future.

KEY POINTS

- CMS regulates the quality of clinical laboratories under CLIA '88.
- FDA regulates medical devices including *in vitro* diagnostics and drugs including blood products.
- The risk-based complexity level of laboratory tests performed determines the requirements for management and testing personnel under CLIA '88.
- Several organizations are approved by CMS to accredit laboratories and to provide external quality control specimens to demonstrate proficiency.
- Workplace safety regulations by OSHA address biological and chemical hazards to laboratory personnel.
- Medicare and Medicaid programs providing healthcare to elderly and low-income citizens have complex requirements for providing diagnosis-based justification for reimbursement.
- The privacy of patient health information must be strictly maintained under HIPAA regulations.

GLOSSARY

501(k) approval FDA approval is based on substantial equivalence to a previously approved device. For *in vitro* diagnostics (IVDs) this includes accuracy, precision, analytic sensitivity, and specificity.

501(k) exemption Exemption is granted when 501(k) approval is not required for demonstrating safety and effectiveness.

Analyte specific reagent Targeted antibodies, ligands, or nucleic acid sequences are categorized into IVD class I, II, or III.

Class I device Low-moderate risk. Quality system regulations and general controls apply; most are exempt from 501(k) approval.

Class II device Moderate-high risk. Quality system regulations, general controls, and special controls apply; most are not exempt from 501(k) approval.

Class III device High risk. Not eligible for 501(k). Quality system regulations, general controls, and premarket approval by FDA are required.

Deemed status Deemed status is granted to a private accreditation organization when CMS deems its programs to meet or exceed CLIA program requirements, and accepts accreditation from that organization instead of CMS or state agency inspection (21 CFR 493.551).

Device classification panels Devices are listed within a medical specialty. Each panel has a number from its rule in 21 CFR. Most IVD tests are under chemistry and toxicology (21 CFR 862), hematology (including blood banking), pathology (21 CFR 864), and microbiology and immunology (21 CFR 866) (https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels [accessed 8 May 2023]).

General controls (GC) GC are requirements for all medical devices which pertain to adulteration, misbranding, registration with FDA, records, quality system regulations, and current Good Manufacturing Practices.

General purpose reagent General purpose reagents are used in multiple tests, such as pH buffers, isotonic solutions, enzyme immunoassay substrates. Class I.

High-risk test High-risk tests are life-sustaining, prevent health impairment, or have potential for risk, and general controls and specific controls are insufficient.

Investigational device exemption (IDE) An IDE grants permission to use an investigational device in a clinical study when seeking FDA device approval.

Premarket approval (PMA) PMA is granted by FDA based on safety and efficacy.

Premarket notification Device makers must notify FDA >90 days before marketing a new device.

Product code A three-letter code is assigned to products that are all approved for the same purpose.

Product Code Classification Database This FDA database permits search by device name, device panel, or product code. If the entire device panel is selected, all of its product codes are displayed and can be reviewed to find the product code for devices performing a specific function (https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database [accessed 8 May 2023]).

Quality system regulations (QSRs) QSRs provide requirements for methods, facilities, and controls in design, manufacturing, labeling, storage, installation, and service according to current Good Manufacturing Practice (cGMP). A rule was pro-

posed in 2022 to harmonize QSR with International Organization for Standardization (ISO) 13485 international device quality requirements (https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices [accessed 8 May 2023]).

Special controls (SCs) SCs include performance standards, premarket data, postmarket surveillance, patient registries, special labeling, and/or guidelines.

Unclassified device Devices marketed prior to 1976, such as some blood grouping reagents, are not classified.

ACKNOWLEDGMENTS

We thank Susan D. Roseff, Denise E. Russell, and Roxanne Mercer, authors of this chapter in the 2nd edition of this volume.

REFERENCES

1. **Hilbert T**, **Kurec A**, **Lifshitz MS**. 2022. General concepts and administrative issues, p 2–12. *In* McPherson RA, Pincus MR (ed), *Henry's Clinical Diagnosis and Management by Laboratory Methods*, 24th ed. Elsevier, Philadelphia, PA.

2. **Congressional Record**. 1967. Clinical Laboratory Licensing Act of 1967 to provide federal standards for laboratories operating interstate. 8 February 1967. *Cong Record* **113 (Part 3)**:2889–2894. https://www.congress.gov/bound-congressional-record/1967/02/08/senate-section. Accessed 5 September 2023.

3. **Bachner P**, **Hamlin W**. 1993. Federal regulation of clinical laboratories and the Clinical Laboratory Improvement Amendments of 1988. Part I. *Clin Lab Med* **13**:739–752, discussion 737–738.

4. **Bachner P**, **Hamlin W**. 1993. Federal regulation of clinical laboratories and the Clinical Laboratory Improvement Amendments of 1988. Part II. *Clin Lab Med* **13**:987–994.

5. **Bogdanovich W.** 1987. False negative: medical labs, trusted as largely error-free, are far from infallible. *Wall Street Journal* 2 February 1987.

6. **Bogdanovich W.** 1987. Lax laboratories: the Pap test misses much cervical cancer through labs' errors. *Wall Street Journal* 2 November 1987.

7. **Department of Health and Human Services.** 1992. Medicare, Medicaid and CLIA programs; regulations implementing the Clinical Improvement Amendments of 1988 (CLIA). *Fed Reg* **57**:7002-7283. Archived at https://www.govinfo.gov/#citation. Accessed 6 September 2023.

8. **Centers for Disease Control and Prevention**. 2022. Clinical Laboratory Improvement Amendments. CLIA Documents. https://www.cdc.gov/clia/clia-documents.html. Accessed 8 May 2023.

9. **Institute of Medicine**. 2011. History of medical-device legislation and regulation in the United States, p 207–278. *In Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*. The National Academies Press, Washington, DC. https://nap.nationalacademies.org/catalog/13150/medical-devices-and-the-publics-health-the-fda-510k-clearance. Accessed 8 May 2023.

10. **Powell SF**. 2018. Changing our minds: reforming the FDA medical device reclassification process. *Food Drug Law J* **73**:177–209.

11. **Berger D.** 1999. A brief history of medical diagnosis and the birth of the clinical laboratory. Part 3. Medicare, government regulation, and competency certification. *MLO Med Lab Obs* **31**:40–42, 44.

12. **Code of Federal Regulations**. Searchable by Title (e.g., 42) and Part (e.g., 493) at https://www.govinfo.gov/#citation. Accessed 6 September 2023.

13. **Westgard JO**. 2019. CLIA Final Rule. Part X: Lies, damn lies, and "equivalent" QC. https://www.westgard.com/cliafinalrule10.htm. Accessed 8 May 2023.

14. **Quintenz A.** 2015. IQCP: a new option for Quality Control. *MLO Med Lab Obs* **47**:6, 8, 10, quiz 11–12. https://www.mlo-online.com/continuing-education/article/13008410/iqcp-a-new-option-for-quality-control. Accessed 8 May 2023.

15. **Centers for Medicare & Medicaid Services**. 2023. Clinical Laboratory Improvement Amendments (CLIA). https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA. Accessed 8 May 2023.

16. **Centers for Medicare & Medicaid Services**. 2023. CLIA statistical tables & graphs. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs. Accessed 8 May 2023.

17. **Centers for Medicare & Medicaid Services**. 2023. Accreditation organizations/exempt states. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Accreditation_Organizations_and_Exempt_States. Accessed 8 May 2023.

18. **Centers for Medicare & Medicaid Services.** 2023. Interpretive guidelines for laboratories. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories. Accessed 8 May 2023.

19. **Senhauser DA**. 1989. Laboratory accreditation, licensure, and regulation, p 339–348. *In* Snyder JR, Senhauser DA (ed), *Administration and Supervision in Laboratory Medicine*, 2nd ed. JB Lippincott Company, Philadelphia, PA.

20. **Clark GB**. 1998. Laboratory regulation, certification, and accreditation, p 369–394. *In* Snyder JA, Wilkinson DS (ed), *Management in Laboratory Medicine*, 3rd ed. Lippincott, Philadelphia, PA.

21. **Appold K.** 2002. ASCP and NCA highlight their certification options. *Vantage Point* **6**:8–10.

22. **Morris S.** 2010. Unification of the NCA and the ASCP Board of Registry. *Clin Lab Sci* **23**:2–4.

23. **Centers for Medicare & Medicaid Services**. 2023. Clinical Laboratory Improvement Amendments (CLIA) State Agency Contacts. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/cliasa.pdf. Accessed 8 May 2023.

24. **US Food & Drug Administration**. 2021. Overview of IVD regulation. https://www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation. Accessed 8 May 2023.

25. **Genzen JR**, **Mohlman JS**, **Lynch JL**, **Squires MW**, **Weiss RL**. 2017. Laboratory-developed tests: a legislative and regulatory review. *Clin Chem* **63**:1575–1584.

26. Genzen JR. 2019. Regulation of laboratory-developed tests. A clinical laboratory perspective. *Am J Clin Pathol* **152**:122–131.

27. US Food & Drug Administration. 2014. Draft guidance for industry, Food and Drug Administration staff, and clinical laboratories. Framework for regulatory oversight of laboratory developed tests (LDTs). https://www.fda.gov/media/89841/download. Accessed 8 May 2023.

28. US Food & Drug Administration. 2017. Discussion paper on laboratory developed tests (LDTs). https://www.fda.gov/media/102367/download. Accessed 8 May 2023.

29. Congress.gov. 2021. H.R.4128 - VALID Act of 2021. 117th Congress (2021–2022). https://www.congress.gov/bill/117th-congress/house-bill/4128/. Accessed 8 May 2023.

30. Graden KC, **Bennett SA**, **Delaney SR**, **Gill HE**, **Willrich MAV**. 2021. A high-level overview of the regulations surrounding a clinical laboratory and upcoming regulatory challenges for laboratory developed tests. *Lab Med* **52**:315–328.

31. U.S. Senate Committee on Health, Education, Labor and Pensions. 2022. Senators Murray, Burr release legislation to support FDA programs to lower costs and spur innovation. https://www.help.senate.gov/chair/newsroom/press/senators-murray-burr-release-legislation-to-support-fda-programs-to-lower-costs-and-spur-innovation-. Accessed 8 May 2023.

32. ASCP. 2023. LDT reform: if Congress won't do it, we will, says FDA. *News*. American Society of Clinical Pathology. April 18, 2023. https://www.ascp.org/content/news-archive/news-detail/2023/04/18/ldt-reform-if-congress-won-t-do-it-we-will-says-fda#. Accessed 8 May 2023.

33. Solomon JM. 1994. The evolution of the current blood banking regulatory climate. *Transfusion* **34**:272–277.

34. Perkins HA, **Busch MP**. 2010. Transfusion-associated infections: 50 years of relentless challenges and remarkable progress. *Transfusion* **50**:2080–2099.

35. US Food & Drug Administration. 2021. Blood establishment registration and product listing. https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/blood-establishment-registration-and-product-listing. Accessed 8 May 2023.

36. US Food & Drug Administration. 2023. Blood and blood products. https://www.fda.gov/vaccines-blood-biologics/blood-blood-products#:~:text=FDA%20inspects%20all%20blood%20facilities,those%20expected%20of%20pharmaceutical%20manufacturers. Accessed 8 May 2023.

37. Association for the Advancement of Blood & Biotherapies. 2023. Donor history questionnaires. https://www.aabb.org/news-resources/resources/donor-history-questionnaires. Accessed 8 May 2023.

38. US Food & Drug Administration. 2023. Recommendations for evaluating donor eligibility using individual risk-based questions to reduce the risk of human immunodeficiency virus transmission by blood and blood products. Guidance for industry. May 2023. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-evaluating-donor-eligibility-using-individual-risk-based-questions-reduce-risk-human. Accessed 4 May 2023.

39. US Food & Drug Administration. 2018. Keeping blood transfusions safe: FDA's multi-layered protections for donated blood. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/keeping-blood-transfusions-safe-fdas-multi-layered-protections-donated-blood. Accessed 8 May 2023.

40. Crowder LA, **Steele WR**, **Stramer SL**. 2020. Infectious disease screening, p 173–227. *In* Cohn CS, Delaney M, Johnson ST, Katz LM (ed), *Technical Manual*, 20th ed. AABB, Bethesda, MD.

41. US Food & Drug Administration. 2020. Bacterial risk control strategies for blood collection estblishments and transfusion services to enhance the safety and availability of platelets for transfusion. Guidance for industry. December 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bacterial-risk-control-strategies-blood-collection-establishments-and-transfusion-services-enhance. Accessed 8 May 2023.

42. Ramsey G. 2016. Hemostatic efficacy of pathogen-inactivated blood components. *Semin Thromb Hemost* **42**:172–182.

43. Rebulla P. 2019. The long and winding road to pathogen reduction of platelets, red blood cells and whole blood. *Br J Haematol* **186**:655–667.

44. Association for the Advancement of Blood and Biotherapies, American Red Cross, America's Blood Centers, Armed Services Blood Program. 2021. Circular of information for the use of human blood and blood components. https://www.aabb.org/docs/default-source/default-document-library/resources/circular-of-information-watermark.pdf. Accessed 8 May 2023.

45. US Food & Drug Administration. 2011. "Computer crossmatch" (computerized analysis of the compatibility between the donor's cell type and the recipient's serum or plasma type). Guidance for industry. April 2011. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-crossmatch-computerized-analysis-compatibility-between-donors-cell-type-and-recipients. Accessed 8 May 2023.

46. Storch EK, **Rogerson B**, **Eder AF**. 2020. Trend in ABO-incompatible RBC transfusion-related fatalities reported to the FDA, 2000-2019. *Transfusion* **60**:2867–2875.

47. Ramsey G. 2020. Landsteiner's legacy: the continuing challenge to make transfusions safe. *Transfusion* **60**:2772–2779.

48. Ramsey G. 2013. Blood component recalls and market withdrawals: frequency, reasons, and management in the United States. *Transfus Med Rev* **27**:82–90.

49. US Food & Drug Administration. 2022. Enforcement reports. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports. Accessed 8 May 2023.

50. US Food & Drug Administration. 2023. Biological product deviations. https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations. Accessed May 8, 2023.

51. US Food & Drug Administration. 2023. Transfusion/donation fatalities.https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/transfusiondonation-fatalities. Accessed 8 May 2023.

52. US Food & Drug Administration. 2020. Regulatory considerations for human cells, tissues, and cellular and tissue-based products: minimal manipulation and homologous use. Guidance for industry and Food and Drug Administration staff. July 2020. https://www.fda.gov/media/109176/download. Accessed 8 May 2023.

53. Association for the Advancement of Blood and Biotherapies. 2021. Circular of information for the use of cellular therapy products. June 2021. https://www.aabb.org/news-resources/resources/cellular-therapies/circular-of-information-cellular-therapy. Accessed 8 May 2023.

54. Hassan S, **West KA**, **Conry-Cantilena K**, **De Giorgi V**. 2022. Regulatory challenges of convalescent plasma collection during the evolving stages of COVID-19 pandemic in the United States. *Transfusion* **62**:483–492.

55. Zhao H, **Devine DV**. 2022. The missing pieces to the cold-stored platelet puzzle. *Int J Mol Sci* **23**:1100.

56. Gammon RR, **Devine D**, **Katz LM**, **Quinley E**, **Wu Y**, **Rowe K**, **Razatos A**, **Min K**, **Reichenberg S**, **Smith R**. 2021. Buffy coat platelets coming to America: are we ready? *Transfusion* **61**:627–633.

57. Dishong D, **Cap AP**, **Holcomb JB**, **Triulzi DJ**, **Yazer MH**. 2021. The rebirth of the cool: a narrative review of the clinical outcomes of cold stored low titer group O whole blood recipients compared to conventional component recipients in trauma. *Hematology* **26**:601–611.

58. Brixner V, **Kiessling AH**, **Madlener K**, **Müller MM**, **Leibacher J**, **Dombos S**, **Weber I**, **Pfeiffer HU**, **Geisen C**, **Schmidt M**, **Henschler R**, **North A**, **Huang N**, **Mufti N**, **Erickson A**, **Ernst C**, **Rico S**, **Benjamin RJ**, **Corash LM**, **Seifried E**. 2018. Red blood cells treated with the amustaline (S-303) pathogen reduction system: a transfusion study in cardiac surgery. *Transfusion* **58**:905–916.

59. Aydinok Y, **Piga A**, **Origa R**, **Mufti N**, **Erickson A**, **North A**, **Waldhaus K**, **Ernst C**, **Lin JS**, **Huang N**, **Benjamin RJ**, **Corash L**. 2019. Amustaline-glutathione pathogen-reduced red blood cell concentrates for transfusion-dependent thalassaemia. *Br J Haematol* **186**:625–636.

60. Gabra MI. 2019. Steps to a safer clinical lab. *Today's Clinical Lab*. https://www.clinicallab.com/steps-to-a-safer-clinical-lab-352. Accessed 8 May 2023.

61. Tweedy JT. 1997. *Healthcare Hazard Control and Safety Management*, p 79–120. HSP Board of Certified Healthcare Safety Management, Bethesda, MD, and Lewis Publishers, Boca Raton, FL.

62. Eden PR, **Hanson JF**. 2018. Medical laboratory safety management. *MLO Med Lab Obs* **50**:26, 29.

63. Centers for Disease Control and Prevention. 2021. Biological risk assessment: general considerations for laboratories. https://www.cdc.gov/safelabs/resources-tools/bio-risk-assessment.html. Accessed 8 May 2023

64. Hart PD. 1999. HAZCOM: the hazard communication standard. *Facil Care* **4**:19–20.

65. Furr AK. 2000. *CRC Handbook of Laboratory Safety*, 5th ed, p 69–197. CRC Press, Boca Raton, FL.

66. National Research Council. 1995. *Prudent Practices in the Laboratory Handling and Disposal of Chemicals*, p 197–212. National Academy Press, Washington, DC.

67. Furr AK. 2000. *CRC Handbook of Laboratory Safety*, 5th ed, p 342–352. CRC Press, Boca Raton, FL.

68. Clinical and Laboratory Standards Institute. 2012. Clinical laboratory safety. Approved Guideline. 3rd ed. CLSI document GP17-A3. Clinical and Laboratory Standards Institute, Wayne, PA.

69. Hicks R. 1989. Basics of clinical laboratory safety, p. 325. *In* Snyder J, Senhauser DA (ed), *Administration and Supervision in Laboratory Medicine*, 2nd ed. JB Lippincott Co, Philadelphia, PA.

70. Brown JW, **Blackwell H**. 1992. Complying with the new OSHA regs. Part III. Compiling employee safety records that will satisfy OSHA. *MLO Med Lab Obs* **24**:45–48.

71. United States Department of Labor, Occupational Safety & Health Administration. 2001. Enforcement procedures for the occupational exposure to bloodborne pathogens. OSHA compliance directive CPL 02-02-069. https://www.osha.gov/enforcement/directives/cpl-02-02-069-0. Accessed 28 July 2023.

72. United States Department of Labor, Occupational Safety & Health Administration. Tuberculosis. https://www.osha.gov/tuberculosis. Accessed 8 May 2023.

73. United States Department of Labor, Occupational Safety & Health Administration. Healthcare: infectious diseases. https://www.osha.gov/healthcare/infectious-diseases. Accessed 8 May 2023.

74. United States Department of Labor, Occupational Safety & Health Administration. COVID-19: Healthcare workers and employers. https://www.osha.gov/coronavirus/control-prevention/healthcare-workers. Accessed 8 May 2023.

75. United States Department of Labor, Occupational Safety & Health Administration. 2021. Protecting workers: guidance on mitigating and preventing the spread of COVID-19 in the workplace. https://www.osha.gov/coronavirus/safework. Accessed 8 May 2023.

76. Congress.gov. 2000. H.R.5178 – Needlestick Safety and Prevention Act. 106th Congress (1999–2000). https://www.congress.gov/bill/106th-congress/house-bill/5178. Accessed 8 May 2023.

77. Lubbert P. 2001. Under OSHA's umbrella. *Adv Adm Lab* **10**:34–39.

78. Occupational Safety and Health Administration. 2023. Bloodborne pathogens and needlestick prevention. U.S. Department of Labor, Washington, DC. https://www.osha.gov/bloodborne-pathogens. Accessed 6 September 2023.

79. US Bureau of Labor Statistics. 2020. Injuries, illnesses, and fatalities. Fact sheet: Occupational injuries and illnesses resulting in musculoskeletal disorders (MSDs). https://www.bls.gov/iif/factsheets/msds.htm. Accessed 6 September 2023.

80. Croce B (ed). 2001. Are you ready for the impact of OSHA's ergonomics standard? *Brief Lab Saf Accredit* **7**(1):1–5.

81. Croce B (ed). 2001. Congress repeals workplace rules, but ergonomics not dead yet. *Brief Lab Saf Accredit* **7**(4):1–5.

82. US Department of Labor. 2002. Occupational injury and illness recording and reporting requirements. US Department of Labor, Washington, DC. https://www.osha.gov/laws-regs/federalregister/2002-12-17. Accessed 6 September 2023.

83. Johnston V. 1997. When pain brings no gain. *Lab Med* **28**:380–386.

84. Center for Devices and Radiological Health. 2008. Medical glove guidance. Guidance for industry and FDA staff. US Department of Health and Human Services, Washington, DC.

85. Parisi CAS, **Kelly KJ**, **Ansotegui IJ**, **Gonzalez-Díaz SN**, **Bilò MB**, **Cardona V**, **Park HS**, **Braschi MC**, **Macias-Weinmann A**, **Piga MA**, **Acuña-Ortega N**, **Sánchez-Borges M**, **Yañez A**. 2021.

Update on latex allergy: new insights into an old problem. *World Allergy Organ J* **14**:100569.

86. National Institute for Occupational Safety and Health. 1997. Preventing allergic reactions to natural rubber latex in the workplace. NIOSH alert, DJJS publication no. 97-135. National Institute for Occupational Safety and Health, Washington, DC.

87. Cook E. 1999. Specimen transport regulation. *Adv Adm Lab* **8**:66–68.

88. Centers for Medicare & Medicaid Services. 2021. National health expenditures: 2020 highlights. https://www.cms.gov/files/document/highlights.pdf. Accessed 8 May 2023.

89. Hartman M, Martin AB, Washington B, Catlin A, The National Health Expenditure Accounts Team. 2022. National health care spending in 2020: growth driven by federal spending in response to the COVID-19 pandemic. *Health Aff (Millwood)* **41**:13–25.

90. Centers for Medicare & Medicaid Services. 2021. Nation's health dollar ($4.3 trillion), calendar year 2021: where it went. https://www.cms.gov/files/document/nations-health-dollar-where-it-came-where-it-went.pdf. Accessed 8 May 2023.

91. Klees BS, **Eckstein ET** III, **Curtis CA**. 2021. Brief summaries of Medicare and Medicaid. Title XVIII and Title XIX of the Social Security Act as of November 15, 2021. https://www.cms.gov/files/document/brief-summaries-medicare-medicaid-november-15-2021-archive-document.pdf. Accessed 8 May 2023.

92. US Department of Health & Human Services. 2022. About the Affordable Care Act. https://www.hhs.gov/healthcare/about-the-aca/index.html. Accessed 8 May 2023.

93. US Census Bureau. 2022. QuickFacts. United States. https://www.census.gov/quickfacts/fact/table/US/PST045221. Accessed 8 May 2023.

94. Centers for Medicare & Medicaid Services. 2023. CMS Fast Facts. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts. Accessed 8 May 2023.

95. Centers for Medicare & Medicaid Services. 2021. CMS Program Statistics – Medicare physician, non-physician practitioner & supplier. https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-service-type-reports/cms-program-statistics-medicare-physician-non-physician-practitioner-supplier. Accessed 8 May 2023.

96. Centers for Medicare & Medicaid Services. 2021. Medicare administrative contractors. https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/MedicareAdministrativeContractors. Accessed 8 May 2023.

97. Centers for Medicare & Medicaid Services. 2023. Medicare coverage – general information. https://www.cms.gov/medicare/coverage/coveragegeninfo. Accessed 8 May 2023.

98. Centers for Medicare & Medicaid Services. 2023. Physician fee schedule. https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched. Accessed 8 May 2023.

99. College of American Pathologists. 2021. Medicare physician feeschedule.https://documents.cap.org/documents/final-2022-medicare-impact-table.pdf. Accessed 8 May 2023.

100. US Department of Health & Human Services, Office of Inspector General. 2023. A roadmap for new physicians. Avoiding Medicare and Medicaid fraud and abuse. https://oig.hhs.gov/compliance/physician-education/. Accessed 8 May 2023.

101. Myles JL, **Cardona DM**, **Klemp T**, **Wooding A**, **Black-Schaffer WS**. 2017. Current valuation of pathology service. *Adv Anat Pathol* **24**:222–225.

102. Cardona DM. 2020. Medicare's Quality Payment Program continues to evolve. What pathologists need to know to succeed. *Arch Pathol Lab Med* **144**:677–678.

103. Cardona DM, **Peditto S**, **Singh L**, **Black-Schaffer S**. 2020. Updates to Medicare's Quality Payment Program that may impact you. *Arch Pathol Lab Med* **144**:679–685.

104. Centers for Medicare & Medicaid Services. 2022. Quality Payment Program. Resource Library. 2022 Quality Payment Program final rule resources. https://qpp.cms.gov/resources/document/804fc384-09f3-4975-8c03-63c1fdd12741. Accessed 6 September 2023.

105. Bocsi GT, **Kang J**, **Kennedy A**, **Singh L**, **Peditto S**, **Cardona DM**. 2020. Developing pathology measures for the Quality Payment Program. Part I. A quest for meaningful measures. *Arch Pathol Lab Med* **144**:686–696.

106. Kelley J, **Patil P**, **Kennedy A**, **Singh L**, **Peditto S**, **Cardona DM**. 2020. Developing pathology measures for the Quality Payment Program. Part II. Overcoming challenges with data capture to maximize reimbursement. *Arch Pathol Lab Med* **144**:697–705.

107. College of American Pathologists. 2023. MIPS for pathologists. https://www.cap.org/advocacy/quality-payment-program-for-pathologists/mips-for-pathologists. Accessed 8 May 2023.

108. Centers for Medicare & Medicaid Services. 2023. Clinical Laboratory Fee Schedule. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched. Accessed 8 May 2023.

109. Sireci AN, **Patel JL**, **Joseph L**, **Hiemenz MC**, **Rosca OC**, **Caughron SK**, **Thibault-Sennett SA**, **Burke TL**, **Aisner DL**. 2020. Molecular pathology economics 101: an overview of molecular diagnostics coding, coverage, and reimbursement: a report of the Association for Molecular Pathology. *J Mol Diagn* **22**:975–993.

110. Centers for Medicare & Medicaid Services. 2016. Medicare clinical diagnostic laboratory tests payment system final rule. https://www.cms.gov/newsroom/fact-sheets/medicare-clinical-diagnostic-laboratory-tests-payment-system-final-rule. Accessed 8 May 2023.

111. Centers for Medicare & Medicaid Services. 2020. Medicare laboratory test expenditures increased in 2018, despite new rate reductions. https://oig.hhs.gov/oei/reports/OEI-09-19-00100.asp. Accessed 8 May 2023.

112. Boothe JF. 2001. HIPAA privacy rule issued: the clock is ticking. Part 1. *Vantage Point* **5**:1–6.

113. Boothe JF. 2001. HIPAA privacy rule issued: the clock is ticking. Part 2. *Vantage Point* **5**:1–9.

114. Department of Health & Human Services. 2022. HIPAA for professionals. https://www.hhs.gov/hipaa/for-professionals/index.html. Accessed 8 May 2023.

115. Department of Health & Human Services. 2023. Summary of the HIPAA security rule. https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html. Accessed 8 May 2023.

116. Goldstein MM, **Pewen WF**. 2013. The HIPAA Omnibus Rule: implications for public health policy and practice. *Public Health Rep* **128**:554–558.

117. US Department of Health & Human Services. 2013. HITECH Act rulemaking and implementation update. https://www.hhs.gov/hipaa/for-professionals/security/guidance/hitech-act-rulemakingimplementation-update/index.html. Accessed 8 May 2023.

118. RiskOptics. 2019. What is the HIPAA omnibus rule of 2013? https://reciprocity.com/resources/what-is-the-hipaa-omnibus-rule-of-2013/. Accessed 8 May 2023.

119. US Department of Health & Human Services. 2013. Breach notification rule. https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html. Accessed 8 May 2023.

120. US Department of Health & Human Services. 2021. Enforcement process. https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/enforcement-process/index.html. Accessed 8 May 2023.

121. US Department of Health & Human Services. 2020. The HIPAA enforcement rule. https://www.hhs.gov/hipaa/for-professionals/special-topics/enforcement-rule/index.html. Accessed 8 May 2023.

122. Charles F. 2021. A guide to new and proposed HIPAA regulations: what to expect. https://blog.charlesit.com/a-guide-to-new-and-proposed-hipaa-regulations-what-to-expect. Accessed 8 May 2023.

123. US Department of Health & Human Services, Office for Civil Rights. 2022. HHS notice and guidance on gender affirming care, civil rights, and patient privacy. https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf. Accessed 8 May 2023.

124. Gupta S, **Imborek KL**, **Krasowski MD**. 2016. Challenges in transgender healthcare: the pathology perspective. *Lab Med* **47**:180–188.

125. Ahmad T, **Lafreniere A**, **Grynspan D**. 2019. Incorporating transition-affirming language into anatomical pathology reporting for gender affirmation surgery. *Transgend Health* **4**:335–338.

126. US Department of Health & Human Services. 2020. HHS proposes modifications to the HIPAA privacy rule to empower patients, improve coordinated care, and reduce regulatory burdens. https://public3.pagefreezer.com/content/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2020/12/10/hhs-proposes-modifications-hipaa-privacy-rule-empower-patients-improve-coordinated-care-reduce-regulatory-burdens.html. Accessed 8 May 2023.

127. Cucoranu IC, **Parwani AV**, **West AJ**, **Romero-Lauro G**, **Nauman K**, **Carter AB**, **Balis UJ**, **Tuthill MJ**, **Pantanowitz L**. 2013. Privacy and security of patient data in the pathology laboratory. *J Pathol Inform* **4**:4.

128. US Food & Drug Administration. 2023. Clinical Laboratory Improvement Amendments (CLIA). https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia. Accessed 8 May 2023.

129. US Food & Drug Administration. 2020. CLIA categorizations. https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-categorizations. Accessed 8 May 2023.

130. Centers for Medicare & Medicaid Services. 2023. Clinical Laboratory Improvement Amendments: how to obtain a CLIA Certificate, including international laboratories. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories. Accessed 8 May 2023.

131. Centers for Disease Control and Prevention and Centers for Medicare & Medicaid Services. IQCP Individualized Quality Control Plan. Developing an IQCP: a step-by-step guide. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf. Accessed 8 May 2023.

132. Department of Health & Human Services and Centers for Medicare & Medicaid Services. 2014. CLIA: Individualized Quality Control Plan: what is an IQCP? https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure13.pdf. Accessed 8 May 2023.

133. US Food & Drug Administration. 2022. Medical device databases. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. Accessed 8 May 2023.

134. US Food & Drug Administration. 2023. CLIA – Clinical laboratory Improvement Amendments. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs//cfCLIA/search.cfm. Accessed 8 May 2023.

135. US Food & Drug Administration. 2018. Product code classification database. https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database. Accessed 8 May 2023.

136. US Food & Drug Administration. 2023. Establishment registration & device listing. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm. Accessed 8 May 2023.

137. US Food & Drug Administration. 2023. MAUDE-manufacturer and user facility device experience. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM. Accessed 8 May 2023.

138. US Food & Drug Administration. 2021. Important reminders about registration and listing. https://www.fda.gov/medical-devices/device-registration-and-listing/important-reminders-about-registration-and-listing. Accessed 8 May 2023.

139. Occupational Safety and Health Administration. 2011. Laboratory safety chemical hygiene plan (CHP). OSHA Fact Sheet. https://www.osha.gov/sites/default/files/publications/OSHAfactsheet-laboratory-safety-chemical-hygiene-plan.pdf. Accessed 8 May 2023.

140. Occupational Safety and Health Administration. 2003. Model plans and programs for the OSHA Bloodborne Pathogens and Hazard Communications Standards. https://www.osha.gov/sites/default/files/publications/osha3186.pdf. Accessed 8 May 2023.

141. Department of Health and Human Services. 2022. Clinical Laboratory Improvement Amendments of 1988 (CLIA) fees; histocompatibility, personnel, and alternative sanctions for certificate of waiver laboratories. *Fed Reg* **87**:44896–44942. https://www.govinfo.gov/content/pkg/FR-2022-07-26/pdf/2022-15300.pdf#page=1. Accessed 6 September 2023.

3

Introduction
Staffing Shortages
Pathology Pipeline
Consolidation of Hospital Systems, Hospitals, and Physician Practices
Health Disparities
The Impact of Technology
Electronic Health Records • Patient Access to Information: Recent Changes to the HIPAA Rules • Molecular Testing
Stewardship of Limited Resources
Supply Chain Instability • Laboratory Utilization • Blood Products
Medicolegal Issues
Malpractice Pre-COVID-19 • Malpractice in the Age of COVID-19 • Public Readiness and Emergency Preparedness Act
Climate of Medical Training
Trainee and Physician Well-Being
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENTS
REFERENCES

The Changing Practice of Medicine

Elizabeth A. Godbey, Susan D. Roseff, and Denise E. Russell

OBJECTIVES

To discuss selected aspects related to the evolution of medicine in recent years:

Staffing

Consolidation of organizations

Patient access to information

Stewardship

Medicolegal issues

Training

To change and to change for the better are two different things.

German Proverb

This chapter's focus is on some of the recent changes in the practice of medicine. Specifically, the chapter discusses staffing shortages, consolidation of hospitals and hospital systems, health disparities, the impact of technology, stewardship of limited resources, medicolegal issues, and new foci of medical training.

Staffing Shortages

Staffing continues to be a critical issue for the American healthcare industry. The National Hospital Association wrote to Congress in March 2022 asking for policy changes to help alleviate the current "national emergency" of healthcare workforce shortages (1). Earlier in 2022, 12% of U.S. hospitals reported "critical" shortages, with 23% of hospitals anticipating shortages (2).

Unfortunately, the laboratory has not escaped these staffing woes. In 2021, the U.S. Bureau of Labor Statistics projected an 11% increase in employment of laboratory technologists and technicians for the 2020–2030 period, with an average of 25,900 openings per year projected during that period (3). Despite increasing demand for laboratory personnel, the number of Medical Laboratory Sciences (MLS) and Medical Laboratory Technology (MLT) training programs in the United States is decreasing (4). Staffing challenges in the laboratory have also been attributed to burnout, retirement (including early retirement), departures to work in other fields, higher compensation available in other fields, added pressures resulting from the coronavirus disease 2019

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch3.

(COVID-19) pandemic, and a lack of awareness by the general population of the profession as a potential career option (5, 6).

Pathology Pipeline

The number of pathology residents and residency programs in the United States has continued to decrease over time. More than 700 pathology residency programs with more than 3,500 residents were active in the U.S. in the 1960s–1970s. By 2013, only 143 programs with about 2,400 residents were still in place (7).

In 2014, the Association of Pathology Chairs (APC) created the Pipeline Subcommittee of the APC Advocacy Committee. Their goal was to research interventions that could increase the number of U.S. medical school graduates who entered the field of pathology. They completed national surveys in 2014 and in 2018 in order to compare characteristics of U.S. medical schools that produce pathology residents with varying frequency. Although they were able to identify some characteristics of medical schools that were associated with fewer or with more medical students entering the specialty of pathology, none of them was statistically significant (7). There is continuing concern among pathologists that decreased exposure to pathology during medical school training may lead to reduced numbers of medical students who pursue pathology as a career choice. In 2019, the College of American Pathologists started the Pathologist Pipeline Initiative with the goal of attracting more medical students into the specialty. They created "Pathologist Pipeline Champions," pathology trainees and pathologists whose goal is to enhance medical student knowledge of, exposure to, and interest in the field of pathology as a career (8). Pathologists and pathology organizations must educate medical students about the importance of pathology in order to avoid a shortage of pathologists.

A shortage of pathologists would have a significant negative impact on patient care. Nationwide systemic changes must occur in order to secure a stable workforce for the future. Without a robust workforce, the critical work of laboratories and of healthcare in general will not be able to continue.

Consolidation of Hospital Systems, Hospitals, and Physician Practices

Consolidation is defined as "the action or process of combining several things into a single more effective or coherent whole" (9). According to a project published by the *Harvard Business Review*, the COVID-19 pandemic will further fuel consolidation in healthcare in the United States (10). A Robert Wood Johnson Foundation (RWJF) project published in 2012 found that market concentration in the U.S. healthcare sector has been on the rise over the past 2 decades. Initially starting with horizontal consolidations, market concentration has now spread to vertical mergers and acquisitions (11).

In the 1990s, consolidation of hospitals and physician practices into systems occurred in response to managed care. During the first decade of the 2000s, this trend slowed. Around 2010, a second wave of consolidations began. This latest wave of consolidations has been attributed to the Affordable Care Act (ACA), the Medicare Access and CHIP Reauthorization Act (MACRA), and financial models. To illustrate the recent increase in healthcare consolidation, from 2002 to 2009 there was an average of 55 mergers and acquisitions reported annually. In 2011, there were 93, 115 in 2017, and 30 in just the first quarter of 2018 (12).

A 2020 publication compared data about physicians and healthcare systems in the U.S. from 2016 to 2018. The authors found that during that 2-year period, the percentage of physicians affiliated with systems increased by 11% (40 to 51%) and that hospital beds associated with systems increased by 3% (88 to 91%). They noted that for-profit systems increased their median number of physicians from 519 to 1,127 and their median number of hospitals from 9 to 23 during this same time period (13).

These processes are classified as horizontal or vertical consolidations. Mergers of companies with similar services are horizontal consolidations (for example, a merger of two hospitals). Mergers of companies that offer services at different points in a process are vertical consolidations (for example, a hospital acquires a private practice). Although hospital mergers decrease duplication of services and result in decreased costs for acquired hospitals, they have been found to increase the average price of hospital services (12).

Concentration in healthcare is where "the market has only a few competitors or when a small number of health care facilities control the market" (10). This generally causes higher prices. A market can also become concentrated over time through consolidation, as competitors combine to form a single provider of care through mergers and acquisitions (10).

Studies such as one done by the RWJF tend to rebut the argument that consolidation improves efficiencies, reduces cost, and leads to better coordination of care. The RWJF study, known as the Synthesis Project, noted a rise in hospital prices across geographic markets and via different data sources. When hospitals merge in already concentrated markets, the price increase can be dramatic, often exceeding 20% (11).

Antitrust laws are "legislation that prevents, or controls trusts or other monopolies with the intention of promoting competition in business" (14). The Federal Trade Commission (FTC) enforces the antitrust laws in healthcare markets to prevent anticompetitive conduct that

would deprive consumers of the benefits of competition (10). In one example, the FTC intervened because hospital acquisitions of physician practices in California drove up prices for primary care services, specialist services, and insurance premiums (11). The FTC recently issued orders to six large insurers (Aetna, Anthem, Cigna, Health Care Service Corporation, and United Healthcare) to provide commercial claims data for hospital inpatient, outpatient, and physician services in 15 states for the period of 2015 to 2020. These directives will provide more detailed evidence about how mergers of physician practices and hospital acquisitions of physician practices affect competition. Once the data have been fully scrutinized, there is the potential to open the door to stricter federal and state oversight (10, 11).

A survey taken in 2021 showed that 70% of physicians are now employed by hospitals or corporate entities (15). Between January 2019 and January 2021, 48,000 physicians quit private practice to take jobs in hospitals and other companies. Several reasons for this exodus from private practice have been cited, including both burnout and the reduction of adequate revenue for private practice physicians during the COVID-19 pandemic (15).

As mentioned above, consolidation, even consolidation between physicians and hospitals, leads to higher prices. This is true with both horizontal and vertical consolidation (16).

Health Disparities

In a report published by the National Institutes of Health (NIH), health disparities are defined as "differences that exist among specific population groups in the United States in the attainment of full health potential that can be measured by differences in incidence, prevalence, mortality, burden of disease and other adverse health conditions" (17). Though the term "disparities" is often used or interpreted to reflect differences among racial or ethnic groups, disparities can exist among other dimensions such as gender, sexual orientation, age, disability status, socioeconomic status, and geographic location (17). Existing evidence shows that there are different health outcomes across and within the groups mentioned above. Health disparities can stem from health inequities, which are described as "systematic differences in the health of groups and communities occupying unequal positions in society that are avoidable and unjust" (18). Please note, the terms for different groups of people used in this section are the terms used by the sources referenced.

Health disparities take on many forms, including higher rates of chronic disease and premature death in some groups of people when compared to rates among other people. Some minority groups, most notably Hispanic immigrants, have better health outcomes than Whites. It should be noted that this paradox seems to diminish with time spent in the United States. In some cases, disparities have shrunk, not because of improvements among minorities, but because of declines in majority groups (19). For example, White females have increased death rates due to suicide and alcohol-related diseases. The recent opioid epidemic, along with the rise of suicide and alcohol-related diseases, has contributed to the first increase in the national death rate in decades as well as the decline in life expectancy among White females (19).

Preterm birth is an important predictor of infant morbidity and mortality and is another health outcome that differs among people from different geographic locations. The National Center for Health Statistics (NCHS) reported that people from Puerto Rico had the highest percentage of preterm singleton births at 9.1%, compared to people from Cuba, who had the lowest rate at 7.2%. Infant mortality rates also vary among different groups of people. For example, the report stated that Native Americans and Alaska Natives had an infant mortality rate that was 60% higher than their White counterparts (20).

Obesity, a condition that has many associated chronic diseases and debilitating conditions, also affects different minorities disproportionately. The study concluded that Hispanic children and adolescents ages 2 to 19 had the highest prevalence of obesity in the United States, at 21.9%. Asians had the lowest at 8.6% (19).

Heart disease and cancer are the leading causes of death across all groups. African Americans are 30% more likely than Whites to die prematurely from heart disease, and African American men are twice as likely to die prematurely from stroke (21). Homicide-related deaths are another example of health disparities. African American men die by homicide at a rate of 4.5%. For male American Indians/Alaska Natives and Hispanic men, the rate of homicide is at least 2% (21).

It is important to know that while there are ample sample sizes with which to draw conclusions about health disparities in some populations, in populations such as Native Americans and Pacific Islanders the sample size is significantly less, which may cause conclusions to be less accurate than the White–African American comparisons (22).

About 3.5% of Americans identify as lesbian, gay, or bisexual, while 0.3% identify as transgender. The lesbian, gay, bisexual, transgender, queer/questioning, intersex, asexual (LGBTQIA+) community belongs to every race, ethnicity, religion, age, and socioeconomic group. Members of the LGBTQIA+ community are at higher risk for substance abuse, sexually transmitted infections (STIs), cancers, cardiovascular disease, obesity, bullying, isolation, rejection, anxiety, depression, and suicide as compared to the general population. Individuals of the LGBTQIA+ community may experience lower quality of care due to stigma or lack of provider awareness of the unique needs of the community (23).

According to Centers for Disease Control and Prevention (CDC) data in 2014, gay and bisexual men accounted for 83% of the new diagnoses of HIV among males aged 13 years and older. Gay men were also at increased risk of various cancers including prostate, testicular, anal, and colon, which might be related to limited culturally sensitive screening services. There was also an increased risk of STIs such as syphilis, human papillomavirus (HPV), and hepatitis in gay men. The risk of breast, ovarian, and endometrial cancers in lesbians and bisexual women was increased. A higher prevalence of obesity was found in African American women and those of lower socioeconomic status (24).

Some LGBTQIA+ individuals may find it difficult to report their sexual identity to clinicians. Some clinicians are not well trained in addressing the concerns of members of the LGBTQIA+ community. Additionally, laboratory reference ranges may not be truly reflective of the individual patient, particularly transgender patients and those receiving gender-affirming therapy. These factors may make some members of this community less likely to seek medical care for fear of cultural insensitivity, judgmental behavior, or suboptimal medical care. Healthcare providers should be educated through training and guidelines for practice to provide comprehensive, scientific, and humane care for this community (25).

A new focus on improving healthcare worker cultural competency for the LGBTQIA+ community continues to expand. Organizations have hoped to improve healthcare access and reduce disparities through employee education. A 2011 survey of medical school deans reported that a third of medical schools did not have any LGBTQIA+ training. This survey also reported that the median time for LGBTQIA+ education (if offered) was 5 hours total. A 2012 survey of family medicine residency programs reported that 42.8% of surveyed programs did not address "gender diverse-specific health care at all." (26). A 2011 paper from the Joint Commission (27) made many recommendations to advance care for this community, among them encouraging hospitals to "incorporate LGBT patient care information in new or existing employee staff training." The New York City Health and Hospitals Corporation initiated a mandatory employee training program in 2011 (28). An increasing number of healthcare training programs now incorporate LGBTQIA+ community training for their learners. For example, the University of Washington School of Medicine now has a designated training track (26). Some 194 hospitals now have optional or mandatory training programs for their employees as well (29, 30).

The American Medical Association (AMA) has taken a leadership role in helping to ensure equal access to healthcare. They have reported that even though there have been improvements in overall health in the United States, certain minority groups experience a lower quality of healthcare and are less likely to receive routine medical care and face higher rates of mortality and morbidity than non-minorities. The AMA continues to encourage physicians to examine their own practices to ensure quality of medical care. The AMA's mission is to achieve health equity by mitigating disparity factors in the patient population. They have taken on an initiative to increase, through advocacy and policies, the number of minority physicians to reflect the diversity of the population of the U.S. The AMA House of Delegates has prioritized the elimination of racial and ethnic disparities as a top importance. The AMA is partnering with the AMA Foundation to help physicians become aware and to manage low health literacy among patients through its public health grants (31).

The Impact of Technology

Electronic Health Records

In 2009, Congress passed the Health Information Technology for Economic and Clinical Health Act (HITECH), which is part of the American Recovery and Reinvestment Act. The purpose of this Act is to incentivize providers, including hospitals and physicians, to adopt electronic health records (EHRs) (32). The Act requires adoption of an EHR and use of it in a meaningful way. A "meaningful way" is not well delineated in the Act. The Act specifies that the EHR must be used for error reduction and cost containment, but leaves the organization to define precisely what this looks like (33).

The EHR stores patient data, but it can also support additional functions such as computer physician order entry (CPOE), tools to support clinical decision making (CDS), and health information exchange (HIE). These tools (CPOE, CDS, HIE) are part of the HITECH requirements for "meaningful use" of health information technology (HIT) in healthcare (34). The CPOE system allows providers to enter orders into a computer rather than on paper and has been popular among providers. Computerization of orders may reduce or eliminate potentially dangerous medical errors caused by poor penmanship or errors in transcription (32).

The EHR allows providers to choose the correct order from a menu of prepopulated orders. There is no doubt that this technology has reduced errors, but it still requires attention to detail to avoid selection of an incorrect drug, dosage, or test. Previous studies suggest that serious medication errors can be reduced by as much as 55% (32, 34) when CPOE is used alone, and by 83% when coupled with CDS that creates alerts based on provider orders. Other benefits, such as improved efficiency and effectiveness, are also realized when CPOE and CDS are linked (34).

Use of an EHR can also facilitate the sharing of patient information through HIE. Using an HIE system allows

patient information to be shared with other organizations. This leads to efficiency and effectiveness because the receiving organization will have a complete picture of the patient's workup, clinical course, and history of treatment. HIE can reduce redundant tests ordered by the receiving physician because the new provider would not otherwise have access to the tests done at the prior facility. Using this function of the EHR allows providers to save time by avoidance of fax machines and paper mail (32, 33).

While there are advantages to the EHR, there are also disadvantages to going electronic. The initial outlay of money to adopt and implement an EHR is often a financial hardship for an organization. Beyond the implementation, there are ongoing maintenance costs. Training staff, including physicians, is a significant cost, but lack of training for proper use of the EHR can cost even more in errors made (32). One industry group estimated hardware, software, services, and telecommunications costs of approximately $19,000 per physician with three or fewer physicians in the practice. This cost goes up for larger practices due to the additional software and training needed (32). Maintenance costs are high due to the need to replace or provide hardware and software frequently associated with system upgrades. New hardware and software require more training (32). Productivity is actually decreased for a period of time following EHR installation. EHRs can cause medical errors if they are not programmed correctly, if end users are not properly trained, or if users become distracted, leading to documentation errors. Another potential downstream consequence of the EHR is patient dissatisfaction. In surveys, patients have complained about redirection of providers' attention from the patient to the EHR. This may be associated with the steep learning curve some providers have when starting to use an EHR (32).

Patient Access to Information: Recent Changes to the HIPAA Rules

The HIPAA Privacy Rule provides privacy protections for individually identifiable health information held by a covered component such as a hospital, or by a business associate of a covered component such as an insurance company (35).

The Information Blocking Rule was enacted in April of 2021. This rule governs how information is shared with patients and third parties. It does not replace HIPAA; instead, it creates an additional set of laws that determines how covered components and covered entities may share protected health information (PHI) (35).

On December 13, 2016, the 21st Century Cures Act (Cures Act) was signed into law (35). On May 1, 2020, the Office of the National Coordinator (ONC), which is the entity that leads national information technology (IT) efforts, issued the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (Final Rule) (35). The Final Rule implements provisions of the Cures Act that are designed to advance interoperability; support the seamless exchange, access, and use of electronic health information (EHI); and address the blocking of information (35). The Cures Act also gives the Department of Health and Human Services (HHS) Office of Inspector General (OIG) authority to investigate claims of information blocking and assess civil monetary penalties against certain actors that engage in information blocking. The information blocking compliance effective date originally set for November 2, 2020, was extended to April 5, 2021 (35).

Information blocking is a process that is likely to interfere with access, exchange, or use of EHI. Information blocking should not be black and white. Instead, the patient's needs and well-being should be considered in balance with strict regulatory compliance. The organization's compliance department should develop structure, policies, and procedures that will lay the foundation for information blocking compliance. Legal counsel with healthcare experience, the organization's privacy officer, and individuals with IT expertise should be included in structuring how the organization will comply with the rules against information blocking (35).

There are four categories of "actor" under the Information Blocking Rules. The four categories include healthcare providers; health IT developers; health information exchanges; and health information networks. If an organization or provider comes under one or more of these categories, it must adhere to the Cares Act Final Rule (35).

At the highest level, the final Information Blocking Rule prohibits these four categories of actors from preventing the exchange, use, or access of EHI. However, embedded in the rules are eight exceptions that empower providers to deny EHI requests without being considered an information blocker (37). To ensure that providers do not inadvertently break the rule, organizations must provide well-defined processes to evaluate and review requests, maintain documentation for compliance purposes, and determine if denials are consistently tailored to one or more of the information blocking exceptions (36).

Molecular Testing

Personalized medicine has received a great deal of national attention in recent years. Molecular testing, and therefore pathology, is at the heart of personalized medicine. Molecular testing is utilized to determine diagnosis and prognosis. It can be used to determine best treatments and interventions, as well as disease monitoring. Molecular testing plays a critical role in identification and management of hematologic malignancies, solid tumors, infections, inherited diseases, and transfusion medicine quandaries. Consensus guidelines for molecular testing

applications are frequently published and updated to provide best practice recommendations for medical practice (38–42).

Stewardship of Limited Resources

Supply Chain Instability

The supply chain is defined as "the sequence of processes involved in the production and distribution of a commodity" (43). More commonly, the supply chain is the part of an organization that identifies, orders, and delivers necessary items to the end user. Hospitals rely on the supply chain to provide the equipment, mostly disposable, necessary to care for patients and to protect staff (44).

In recent years, COVID-19 has wreaked havoc on the supply chain of most, if not all, hospitals. One of the most disruptive shortages during this period has been personal protective equipment (PPE). Hospitals needed to increase their supply of PPE rapidly and dramatically when the COVID-19 pandemic hit in 2020. Sourcing products in the quantity and quality necessary placed hospital executives in uncharted waters (45). Much of the PPE that is purchased for hospitals comes from other countries. While hospitals ordered "as much as you can get as soon as you can get it," the countries that were producing the PPE needed it as well (44). Hospitals generally maintain emergency supplies, but most did not have the amount necessary for the prolonged COVID-19 disruption (46). The trend leading into the pandemic onset was to maintain only a certain volume in stock (to limit financial investment). This tenet is now being rethought by organizations due to events surrounding COVID-19 (45).

The makers of PPE in the United States quickly began to increase production but could not meet demand. Hospitals were contacted by vendors willing to sell PPE (usually gloves and masks) at double or triple the usual cost. One estimate is that demand for PPE increased by 1,700% during this time period (46); price gouging became common. To keep up with demand for PPE, many hospitals resorted to canceling elective surgeries. Some health systems shut down nonessential departments and restricted visitors. During the height of the pandemic, some manufacturers began making new products based on their existing resources. For example, some clothing manufacturers produced PPE gowns and/or masks, and some distilleries made hand sanitizer.

To prepare for future pandemics and other public health crises, hospitals must be cognizant of balancing cost control and emergency preparedness (45). If traditional distributors cannot meet the growing demand of a hospital system, other fair and equitable sources can be used (including equipment clearinghouses and safe crowdsourcing platforms, if supplies meet regulatory and quality standards). Technology could be used to create real-time, visible platforms that could allow for the seamless redistribution of resources across all levels of the supply chain (45).

Laboratory Utilization

The United States continues to try to find new methods to both improve quality in healthcare and reduce unnecessary costs. Creating utilization or stewardship committees has been successful to reduce unnecessary blood transfusion, antibiotic usage, and laboratory testing. Stewardship, as defined by Merriam-Webster, is "1: the office, duties, and obligations of a steward; 2: the conducting, supervising, or managing of something *especially*: the careful and responsible management of something entrusted to one's care" (47).

Anecdotally, 70% of medical decisions are based upon laboratory tests, though this might be closer to 70–85% (48, 49). In 2013 the American Hospital Association (AHA) released a white paper about appropriate use of medical resources (50). One theme of the paper is to diminish the use of resources for interventions that have no proven benefit and only serve to increase the cost of services. The white paper discusses the shift from volume-based to value-based care, which will in turn shift payment incentives, and then medical practice. The paper shares examples of scenarios where doing more and increasing the number of tests may not cause a reduction in death or improvement in outcomes.

Antimicrobial stewardship has been shown to improve patient outcomes, reduce morbidity, and reduce the incidence of antimicrobial resistance. This approach provides benefit to the individual patient as well as the general population. By choosing the correct drug, at the correct dose, the first time, there will be a reduction in unnecessary costs, with the best outcomes (51).

Though stewardship of healthcare resources is the responsibility of everyone in the industry, laboratory professionals, pathologists, and laboratory scientists have a responsibility to assure the appropriate use of resources in collaboration with their clinical partners. As Eaton et al. (52) point out, inappropriate testing is one of the foundations of the increasing cost of laboratory services. Some inappropriate tests are unnecessary and repetitive, such as some daily laboratory tests, that are ordered on a recurring basis without clinical utility (for example, some standing orders). This challenge is multifactorial, stemming from lack of knowledge of the cost of testing, fear of lawsuits, diagnostic uncertainty, lack of training, and lack of feedback. When a test is performed without accompanying clinical signs and symptoms, its positive predictive value may not be known. Therefore, it will be difficult to correctly interpret the results, possibly leading to incorrect diagnoses and treatments. While repetitive testing of the same analyte will improve sensitivity, there is a concomitant reduction in specificity.

To use the words of the author, "too many good tests are the same as a bad test" (53).

In 2012 the American Board of Internal Medicine (ABIM) Foundation and the nonprofit consumer organization Consumer Reports launched the "Choosing Wisely" campaign, found at https://www.choosingwisely.org (54). One of the core missions of this campaign is to involve patients and clinicians in discussions to help direct care that is supported by evidence, is not duplicative of other tests or procedures already received, is free from harm, and is truly necessary. To facilitate discussion, the group created materials that were oriented toward a lay population. Thirty-five specialty organizations participated and created a list of tests and recommendations that highlighted treatments/tests that may not be necessary. The groups were asked to list tests that appeared to be overused and met specific criteria. For a full list of the participating organizations and their measures, please see the Choosing Wisely campaign's website (54).

Myriad studies inspect methods to curb unnecessary laboratory testing. As with any behavioral intervention, it is important to try to find ways to create processes that can be sustained over time. Different institutions have looked at the effectiveness of education, audit and feedback of practitioners' ordering practices, and use of the EHR to help restrict ordering of certain tests (52, 53).

Education. Education of ordering providers should encompass medical necessity, evidence-based indications, and costs of tests. Eaton et al. showed that education can cause a statistically significant reduction of the number of test orders for those tests that were studied (52). Unfortunately, this change was not sustainable. Displaying cost alone yielded mixed results. Some of the challenges of using an educational approach are knowledge retention, subsequent use of knowledge, needs for reeducation, and continuous education of new staff. Though face-to-face interventions might be the most effective, they are time-consuming and could become confrontational. Also, if the intervention occurs after the sample has been drawn and processed, the test is not avoided.

The utilization patterns of providers can be shared with them as a source of intervention in the form of "report cards." Competition has been found to be an effective strategy to improve the motivation to change behavior by anonymously sharing data among peers (52, 53, 55).

Role of IT. Taking advantage of a hospital's IT resources can be both proactive and enduring and more effective than some of the passive approaches. By incorporating best practices into the order entry system, ordering patterns can be changed. An effective strategy is to create hard stops (programmed situations where ordering cannot proceed). Hard stops can facilitate consultation with a pathologist to determine if the test is medically necessary; if clinically indicated, laboratorians can override the hard stop. Hard stops may be utilized for expensive tests or tests that are frequently ordered incorrectly. Soft stops (messages that can be easily overridden) are not effective over time. The laboratory can design rules to place the "correct" test first in a list, such as the correct vitamin D order. Also, specific tests can be hidden or only ordered by specific groups of people. The EHR can also designate approved ordering providers or departments for specific tests, while blocking others from approval. In these scenarios, pop-ups are frequently used to inform providers of the appropriate referral pathway. For example, a pop-up may inform a primary care practitioner that approval by an infectious disease (ID) specialist is required to order a particularly obscure ID laboratory test (53, 55–58).

Pop-ups have advantages and disadvantages. Although they are helpful if used sparingly, frequent use can cause alert-fatigue, rendering the pop-ups ineffective. One helpful use of a pop-up is to prevent reordering of tests that have already been ordered within a designated time period. The EHR can alert the ordering provider of the date the test was ordered and, if available, the most recent results. For example, when ordering a genetic test for an inherited disorder, the message can give the result and state that the test should only be done once in a patient's lifetime. Tests that are no longer ordered or available should be promptly removed from the order entry catalog. Harnessing the EHR to integrate algorithms and decision support tools has been shown to positively change ordering behavior (52, 53, 55–58).

Laboratory formularies and utilization committees. A very robust way to change behaviors and get buy-in from key stakeholders is to create a laboratory formulary. The formulary will be a living document that lists approved tests, tests not orderable, and those orderable needing special approvals. With the input of a wide variety of specialists, a stewardship committee can vet the medical necessity of new tests being requested. For tests that are high cost and/or being sent to labs not currently contracted with the institution, hard stops can be set up. This process will bring any new test to the attention of the committee, where it can then undergo review. There has been success with incorporating clinical pathologists or genetic counselors into utilization committees as the "gatekeepers" for approval of orders for high-cost genetic tests. Not only has this been shown to reduce cost, but it ensures that the correct test is used at the correct time, improving patient outcomes (58, 59).

Underuse of tests that add value and contribute to patient care outcomes should be evaluated by the committee as well. There are some appropriate and useful screening tests that should not be withheld due to cost (52, 53, 55). The number of available tests continues to rise over time,

a trend that began a few decades ago (55, 58–60); a laboratory stewardship committee can help monitor usage of tests and focus resources on best testing practices.

The commitment of hospital leadership, especially the chief medical officer, is imperative for the success of stewardship efforts (55). Leadership must empower the committee to make decisions and must provide the necessary resources to operate effectively. The membership must be composed of a multidisciplinary group with expertise in the medical specialty areas to be discussed, but also requires personnel with expertise in IT, billing/finance, and analytics. Both a bedside physician and a laboratory physician should serve as cochairs of these committees. By developing a program that can track data, the effectiveness of their interventions can be measured. Without the ability to gather data to review the impact of interventions, this might not be a successful endeavor (52, 53, 55). There should be a consistent method and time frame to periodically assess the impact of each intervention. Interventions and their measures must be honed on an ongoing basis. Some of the strongest interventions that impact laboratory stewardship combine a variety of approaches to impact utilization and cost. Successful interventions should be shared with senior leadership and organization-wide (52, 53, 55).

Diagnostic management teams. Another multidisciplinary approach to improve the appropriate use of laboratory tests is a "diagnostic management team" (DMT). A DMT engages key stakeholders in laboratory stewardship and assures the best use of laboratory resources in the service of patients. These teams are composed of laboratory medicine physicians and scientists who have expertise in the specific DMT topic areas. They consult with the healthcare providers who are at the patient bedside. For example, by bringing these different medical professionals together in a coagulation DMT at Vanderbilt University Medical Center and then at University of Texas Medical Branch at Galveston, there were improvements in efficiency in diagnosis, reduction in cost, reduction in diagnostic errors, and demonstration of improved outcomes (61, 62).

Blood Products

Blood products for transfusion in the United States come from unpaid volunteer donors. Blood products are limited, precious resources that cannot be created in a factory from purchased supplies. The U.S. blood supply depends on donations from altruistic donors. Transfusion medicine specialists have worked with their medical and surgical colleagues for years to provide blood products to patients who need them, and to utilize these precious resources only for those patients who truly need them. These preservation interventions are varied, but examples include prospective blood order audits, electronic medical record messaging, education outreach, and hospital policy changes. Shortages of blood products have occurred with some predictable regularity for years. Shortages are expected during times of low donor turnout (for example, summer or winter holidays when many donors are traveling). However, the COVID-19 pandemic resulted in severe, long-term blood product shortages the likes of which had never been seen before. Many locations that had (prepandemic) generated large-scale donations closed during the pandemic. Many schools and businesses stopped hosting collection drives. Some donors may have stopped donating due to their desire to avoid contact with other people in a donor center, or to entering lockdown/quarantine periods. The FDA reduced several blood donation deferral periods in April 2020, stating that ". . .early implementation of the recommendations in this guidance may help to address significant blood shortages that are occurring as a result of a current and ongoing public health emergency" (63). For example, the previous 12-month-long deferrals for recipients of blood transfusions, recipients of tattoos in unlicensed facilities, men who have sex with men (MSM), and women who have sex with MSM were all reduced to 3-month deferrals. Blood collectors made many nationwide efforts to attract donors, including gifts, lottery entries for large prizes, and pleas in lay media (64, 65). Several states proposed tax credits for blood donors or employers who hosted blood drives. Oklahoma began income tax credits on November 1, 2021, for employers who host blood drives (66). Despite efforts to increase donor turnout, severe shortages continued. The American Red Cross began rationing red blood cell units to hospitals on December 16, 2021; termed "thresholds," these limits were softened on March 14, 2022. The medical community must continue to do its best to appropriately manage the limited blood supply available to best meet needs of patients, and collection facilities must continue to strive to maintain collection volumes to support their hospital customers.

Medicolegal Issues

Malpractice Pre-COVID-19

Before the COVID-19 pandemic, recovery for a plaintiff's verdict was steadily increasing. Severity of malpractice cases has been rising since at least the 1970s (67). More recently, there has been a sharp increase in outlier verdicts. An outlier verdict is one that exceeds common policy limits and often sets records for the verdict dollar amount (67). For example, from 2014 to 2018, the number of malpractice awards greater than $25 million more than tripled. Similarly, from 2010 to 2019, the average of the costliest 100 jury awards for medical malpractice cases rose by almost half (67).

Why the dramatic rise, when there have been strides made in patient safety and the overall frequency of

claims has dropped? One insurer owned by physicians, The Doctors Company, states that they have seen a drop in claims from a high of 17 claims per 100 physicians in 2000 to fewer than 7 claims per 100 physicians in 2020, which was the start of the COVID-19 pandemic (67). One reason given for the award increase is the consolidation of healthcare—perhaps larger corporate defendants, almost always with very high policy limits, make attractive deep pockets in the eyes of sympathetic juries (67).

Malpractice in the Age of COVID-19

As of 2020, there were already 20% fewer claims than expected in the 18 to 24 months prior to the pandemic (67). Malpractice claims take time to surface; months or years may elapse before a malpractice claim is made (68). Therefore, it will likely be years before we learn about cases from just before the pandemic, and perhaps even later for those claims that may have occurred during the pandemic.

Other factors may have also affected the number of malpractice claims in the era of COVID-19. The pandemic closed courts and legal offices. Perhaps some people were reluctant to meet with attorneys for fear of becoming ill. Malpractice insurers feel certain that pandemic-related claims will be filed (68).

Public Readiness and Emergency Preparedness Act

To encourage the expeditious development and deployment of medical countermeasures during a public health emergency, the Public Readiness and Emergency Preparedness Act (PREP Act), signed into law in 2005, authorizes the Secretary of HHS to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines (69). On February 4, 2020, HHS declared COVID-19 to be a public health emergency and activated the PREP Act. Under this declaration and its amendments, covered persons are generally immune from legal liability (i.e., they cannot be sued in court for money damages) for losses relating to the administration or use of covered countermeasures against COVID-19. The sole exception to the PREP Act immunity is for death or serious physical injury caused by "willful misconduct" (69). Willful misconduct means "intentional disregard of good and prudent standards of performance or proper conduct with knowledge that it is likely to result in any injury to any person or persons or loss or damage of property" (69).

Federal laws such as the PREP Act may preempt state tort laws, as well as other state and federal laws in certain contexts. In the PREP Act, Congress made the judgment that, in the context of a public emergency, immunizing certain persons and entities from liability was necessary to ensure that potentially life-saving countermeasures would be effectively developed, deployed, and administered (69).

Climate of Medical Training

Trainee and Physician Well-Being

The well-being of medical trainees has been an ongoing focus of the medical education community for many years now. Perhaps the most recent large-scale examples of the focus on medical trainee wellness are the various iterations of mandated resident duty hour changes that occurred in 2003, in 2010, and again in 2017 (70–72). The purpose of the 2017 Accreditation Council for Graduate Medical Education (ACGME) revision of its Common Program Requirements is to "emphasize that psychological, emotional, and physical well-being are critical in the development of the competent, caring, and resilient physician" (73). Also in 2017, the National Academy of Medicine established the Action Collaborative on Clinician Well-Being and Resilience, a group whose goal is to focus on improving trends of clinician burnout. The COVID-19 pandemic inspired a renewed interest in physician and trainee wellness. The pandemic altered everything about clinical education. In many places, student clinical rotations and shadowing opportunities were canceled in favor of sending medical students home in order to safeguard their health. Elective procedures were limited or canceled across the U.S., which reduced trainees' exposure to those procedures. PPE supply was limited, further limiting opportunities for patient care experiences. Limited on-site and in-hospital activities, paired with social distancing guidelines, required creative solutions. Technology was utilized for virtual lectures, small groups, and even telemedicine (74). At the opposite end of the spectrum, some medical schools graduated senior medical students early so that they could join the physician workforce on an accelerated schedule (75, 76). Multiple resources for trainee wellness are available online from the ACGME, the Association of American Medical Colleges (AAMC), and the AMA (77–80).

SUMMARY

The practice of medicine is continually evolving. Recent years have seen particularly prominent changes concerning healthcare staffing, consolidation of health organizations, patient access to information, stewardship of limited resources, medicolegal issues, and healthcare personnel training. Just as it has since its very beginnings, the practice of medicine will continue to evolve and change long after this book is printed.

KEY POINTS

- Nationwide changes are needed to secure a stable healthcare workforce for the future.
- Healthcare organizations, hospitals, and physician practices continue to consolidate.

- The medical community is working to reduce healthcare disparities.
- Education, IT interventions, and maintaining a laboratory test formulary can improve patient outcomes and reduce cost.

GLOSSARY

Accreditation Council for Graduate Medical Education (ACGME) Professional organization responsible for accrediting post–medical school training.

Affordable Care Act The Affordable Care Act, formally known as the Patient Protection and Affordable Care Act and colloquially known as Obamacare, is a landmark U.S. federal statute enacted by Congress and signed into law by President Barack Obama on March 23, 2010.

American Board of Internal Medicine (ABIM) The certifying organization for the field of internal medicine.

American Medical Association (AMA) A professional group that publishes research to advance public health and advocates for the interests of physician-members. Primary interests include patient safety and quality improvement, among many others. Physicians, resident physicians, and medical students can all apply for membership in the AMA.

Antitrust laws In the United States, antitrust law is a collection of mostly federal laws that regulate the conduct and organization of businesses to promote competition and prevent unjustified monopolies.

Clinical decision support (CDS) Provides clinicians, staff, patients, or other individuals with knowledge and person-specific information, intelligently filtered, or presented at appropriate times, to enhance health and health care.

College of American Pathologists (CAP) Association of pathologists dedicated to fostering excellence in pathology and laboratory medicine. Recognized leader in providing laboratory inspection and accreditation programs.

Computerized provider order entry (CPOE) The process of providers entering and sending treatment instructions—including medication, laboratory, and radiology orders—via a computer application rather than paper, fax, or telephone.

Cures Act The 21st Century Cures Act is a federal law enacted by the 114th United States Congress in December 2016. The law authorized $6.3 billion in funding, mostly for the National Institutes of Health.

Defendant An individual, company, or institution that is accused of wrongdoing.

Diagnostic management team (DMT) A multidisciplinary approach to improve the appropriate use of laboratory tests that includes a broad group of stakeholders.

The Doctors Company A physician-owned company that insures doctors primarily for medical malpractice claims.

Electronic medical record (EMR) An electronic medical record is a digital version of a patient's paper chart. EMRs are real-time, patient-centered records that make information available instantly and securely to authorized users. While an EMR does contain the medical and treatment histories of patients, an EMR system is built to go beyond standard clinical data collected in a provider's office and can be inclusive of a broader view of a patient's care.

Electronic health record (EHR) Another term for the EMR, or electronic medical record.

Federal Trade Commission (FTC) The FTC's mission is to protect the public from deceptive or unfair business practices and from unfair methods of competition, through law enforcement, advocacy research, and education.

Graduate medical education (GME) Specialty or subspecialty training occurring after medical school.

Health Information Technology for Economic and Clinical Health (HITECH) Act The HITECH Act is part of the American Recovery and Reinvestment Act (ARRA) of 2009 and creates incentives related to healthcare information technology, including incentives for the use of electronic medical record (EMR) systems among providers.

Health information exchange (HIE) The mobilization of healthcare information electronically across organizations within a region, community, or hospital system. Participants in data exchange are called, in the aggregate, health information networks.

Horizontal consolidation or horizontal integration Terms used to describe the process of merging the same type of business or product line at the same stage of production in a single industry.

Infant mortality The death of an infant before his or her first birthday. The infant mortality rate is the number of infant deaths for every 1,000 live births.

Information blocking rule Information blocking is a practice by an individual that is likely to interfere with the access, exchange, or use of electronic health information (EHI), except as required by law or specified in an information-blocking exception.

Laboratory formulary A document that is frequently revised, which provides a list of tests approved by the Laboratory Utilization or Stewardship Committee. A group of representatives of medical specialties determines the medical necessity for tests.

Medical scribe An allied health paraprofessional, often a medical student, who specializes in charting physician-patient encounters in real time, such as during medical examinations. They also locate information and patients for physicians and complete forms needed for patient care.

Mergers and acquisitions Business transactions in which the ownership of companies and other business organizations is transferred or consolidated with another company or business organization.

Office of Inspector General (OIG) The OIG is responsible for oversight of the United States Department of Health and Human Services. OIG's mission is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve.

Office of the National Coordinator (ONC) The Office of the National Coordinator for Health Information Technology is a staff division of the Office of the Secretary within the U.S. Department of Health and Human Services.

Outlier verdict A verdict that has circumstances outside the usual characteristics or parameters for that type of legal case.

Plaintiff In a lawsuit the individual who is initiating the lawsuit is the plaintiff.

Personal protective equipment (PPE) PPE is equipment worn to minimize exposure to hazards that cause serious workplace injuries and illnesses. These injuries and illnesses may result from contact with chemical, radiological, physical, electrical, mechanical, or other workplace hazards. PPE may include items such as gloves, safety glasses and shoes, earplugs or muffs, hard hats, respirators, coveralls, vests, and full-body suits.

PREP (Public Readiness and Emergency Preparedness) Act The PREP Act was issued specifically to provide liability protections to manufacturers, distributors, states, localities, licensed healthcare professionals, and other qualified persons who administer COVID-19 countermeasures such as masks, vaccines, or medications, among other treatments. The Act has been amended several times to expand liability protections, including prior amendments to cover licensed healthcare professionals who cross state borders and federal response teams who aid with care of COVID-19 patients.

Robert Wood Johnson Foundation The Robert Wood Johnson Foundation is an American philanthropic organization. It is the largest one focused solely on health. Based in Princeton, New Jersey, the foundation focuses on access to healthcare, public health, health equity, leadership and training, and changing systems to address barriers to health.

Supply chain The series of steps necessary to produce a good or service.

Stewardship "1: the office, duties, and obligations of a steward; 2: the conducting, supervising, or managing of something *especially*: the careful and responsible management of something entrusted to one's care" (47).

Vertical consolidation Vertical consolidation is when a company buys another company that performs a service or produces a good on a different part of the supply chain.

ACKNOWLEDGMENTS

The authors would like to thank Andrew Fletcher and Gary Procop for their informative laboratory stewardship presentations and publications over the years.

REFERENCES

1. Gooch K. 2022. Healthcare workforce challenges a national emergency, hospitals say. https://www.beckershospitalreview.com/workforce/healthcare-workforce-challenges-a-national-emergency-hospitals-say.html. Accessed 4 March 2022.

2. Plescia M, **Gooch K**. 2022. 12% of US hospitals critically understaffed, 23% anticipate shortages: numbers by state. https://www.beckershospitalreview.com/workforce/12-of-us-hospitals-critically-understaffed-23-anticipate-shortages-numbers-by-state.html. Accessed 4 March 2022.

3. Bureau of Labor Statistics. 2023. U.S. Department of Labor, Occupational Outlook Handbook, Clinical Laboratory Technologists and Technicians. https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm. Accessed 6 March 2022.

4. Scott K. 2020. Solving the clinical laboratory workforce shortage. https://www.clinicallabmanager.com/trends/laboratory-staffing/solving-the-clinicallaboratory-workforce-shortage-23189. Accessed 4 March 2022.

5. Rohde RE. 2022. The omicron variant is deepening severe staffing shortages in medical laboratories across the U.S. https://www.clinicallab.com/the-omicron-variant-is-deepening-severe-staffing-shortages-in-medical-laboratories-across-the-us-26190. Accessed 4 March 2022.

6. Gilligan P, **Rohde RE**. 2021. Clinical and public health laboratories need you. American Society for Microbiology. https://asm.org/Articles/2021/November/Clinical-and-PublicHealth-Laboratories-Need-You. Accessed 4 March 2022.

7. Naritoku WY, **Furlong MA**, **Knollman-Ritschel B**, **Kaul KL**. 2021. Enhancing the pipeline of pathologists in the United States. *Acad Pathol* **8**:23742895211041725.

8. College of American Pathologists. 2023. Pathologist Pipeline Champions. https://www.cap.org/member-resources/resources-for-medical-students/pathologist-pipeline-champions. Accessed 5 March 2022.

9. Oxford English Dictionary. 2023. Consolidation. https://www.oed.com. Accessed 23 March 2022.

10. Gustafson L, **Blumenthal D**. 2021. The pandemic will fuel consolidation in U.S. health care. *Harvard Bus Rev*. https://hbr.org/2021/03/the-pandemic-will-fuel-consolidation-in-u-s-healthcare. Accessed 4 March 2022.

11. Gaynor M, **Town R**. 2012. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9, June 2012. https://www.researchgate.net/publication/283910115_The_Impact_of_Hospital_Consolidation_-_Update. Accessed 4 March 2022.

12. NCCI Insights. 2018. The impact of hospital consolidation on medical costs. July 11, 2018. https://www.ncci.com/Articles/Pages/II_Insights_QEB_Impact-of-Hospital-Consolidation-on-Medical-Costs.aspx. Accessed 4 March 2022.

13. Furukawa MF, **Kimmey L**, **Jones DJ**, **Machta RM**, **Guo J**, **Rich EC**. 2020. Consolidation of providers into health systems increased substantially, 2016–2018. *Health Affairs* **39**. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00017. Accessed 16 March 2022.

14. LaPointe J. 2020. No quality of care benefit from hospital acquisitions. RevCycle Intelligence, *Practice Management News*. https://revcycleintelligence.com/news/no-quality-of-care-benefit-from-hospital-acquisitions-study-finds. Accessed 21 March 2022.

15. Bannow T. 2021. Nearly 70% of U.S. physicians now employed by hospitals or corporations, report finds. *Modern Healthcare*. https://www.modernhealthcare.com/providers/nearly-70-us-physicians-now-employed-hospitals-or-corporations-report-finds. Accessed 18 March 2022.

16. Schwartz K, Lopez E, Rae M, Neuman T. 2020. What we know about provider consolidation. Kaiser Family Foundation (KFF). https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/. Accessed 19 March 2022.

17. Crews DC, Patzer RE, Cervantes L, Knight R, Purnell TS, Powe NR, Edwards DP, Norris KC. 2022. Designing interventions addressing structural racism to reduce kidney health disparities: A report from a National Institute of Diabetes and Digestive and Kidney Diseases workshop. *J Am Soc Nephrol* **33**:2141–2152.

18. Graham H. 2004. Social determinants and their unequal distribution: clarifying policy understandings. *Milbank Q* **82**:101–124.

19. US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics. 2016. Health, United States, 2015. https://www.cdc.gov/nchs/data/hus/hus15.pdf. Accessed 22 March 2023.

20. US Department of Health and Human Services, Office of Minority Health. 2023. Infant mortality and African Americans. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=23. Accessed 15 March 2022.

21. Centers for Disease Control and Prevention. 2022. Leading causes of death in males, United States. https://www.cdc.gov/minorityhealth/lcod/index.htm. Accessed 22 October 2023.

22. Bauer UE, Plescia M. 2014. Addressing disparities in the health of American Indian and Alaska Native people: the importance of improved public health data. *Am J Public Health* **104**(Suppl 3):S255–S257.

23. Hafeez H, Zeshan M, Tahir MA, Jahan N, Naveed S. 2017. Health care disparities among lesbian, gay, bisexual, and transgender youth: a literature review. *Cureus* **9**:e1184.

24. Bowen DJ, Boehmer U. 2007. The lack of cancer surveillance data on sexual minorities and strategies for change. *Cancer Causes Control* **18**:343–349.

25. Morris M, Cooper RL, Ramesh A, Tabatabai M, Arcury TA, Shinn M, Im W, Juarez P, Matthews-Juarez P. 2019. Training to reduce LGBTQ-related bias among medical, nursing, and dental students and providers: a systematic review. *BMC Med Educ* **19**:325–338.

26. Wang KS, Sutherland M, Gibson AW, Gobillot T, Conley E, Matsumoto K. 2021. A guide to creating a gender-affirming environment through a community lens approach. *Prim Care* **48**:227–241.

27. The Joint Commission, The California Endowment. 2011. Advancing effective communication, competence, and patient- and family-centered care for the lesbian, gay, bisexual, and transgender (LGBT) community: a field guide. https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/health-equity/lgbtfieldguide_web_linked_verpdf.pdf?db=web&hash=FD725DC02CFE6E4F21A35EBD839BBE97&hash=FD725DC02CFE6E4F21A35EBD839BBE97. Accessed 6 March 2022.

28. NYC Health + Hospitals. 2011. Press release: HHC will adopt mandatory cultural competence training for staff to improve the health of lesbian, gay, bisexual, transgender New Yorkers. https://www.nychealthandhospitals.org/pressrelease/hhc-will-adopt-mandatory-cultural-competence-training-for-staff-to-improve-the-health-of-lesbian-gay-bisexual-transgender-new-yorkers/. Accessed 6 March 2022.

29. VCU Health. VCU Health online courses. https://ocpe.vcu.edu/online#

30. Roth LT, Friedman S, Gordon R, Catallozzi M. 2020. Rainbows and "ready for residency": integrating LGBTQ health into medical education. *MedEdPORTAL* **16**:11013.

31. American Medical Association. 2023. Reducing disparities in health care. https://www.ama-assn.org/delivering-care/patient-support-advocacy/reducing-disparities-health-care. Accessed 1 March 2022.

32. Menachemi N, Collum TH. 2011. Benefits and drawbacks of electronic health record systems. *Risk Manag Healthc Policy* **4**:47–55.

33. Office of the National Coordinator. 2023. Department of Health and Human Services. http://www.healthIT.gov/data. Accessed 20 October 2023.

34. Bates DW, Leape LL, Cullen DJ, Laird N, Petersen LA, Teich JM, Burdick E, Hickey M, Kleefield S, Shea B, Vander Vliet M, Seger DL. 1998. Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. *JAMA* **280**:1311–1316.

35. HealthIT.gov. 2022. Information blocking. https://www.healthit.gov/topic/information-blocking. Accessed 22 March 2022.

36. American Medical Association. 2021. How do I comply with information blocking and where do I start? https://www.ama-assn.org/system/files/2020-11/info-blocking-compliance.pdf. Accessed 4 March 2022.

37. Slivochka S, Warner W. 2021. Understanding the eight exceptions to information blocking. *Journal of AHIMA*. https://journal.ahima.org/page/understanding-the-eight-exceptions-to-information-blocking. Accessed 1 March 2022.

38. Eggener SE, Rumble RB, Armstrong AJ, Morgan TM, Crispino T, Cornford P, van der **Kwast T, Grignon DJ, Rai AJ, Agarwal N, Klein EA, Den RB, Beltran H**. 2020. Molecular biomarkers in localized prostate cancer: ASCO Guideline. *J Clin Oncol* **38**:1474–1494.

39. Sepulveda AR, Hamilton SR, Allegra CJ, Grody W, Cushman-Vokoun AM, Funkhouser WK, Kopetz SE, Lieu C, Lindor NM, Minsky BD, Monzon FA, Sargent DJ, Singh VM, Willis J, Clark J, Colasacco C, Rumble RB, Temple-Smolkin R, Ventura CB, Nowak JA. 2017. Molecular biomarkers for the evaluation of colorectal cancer: guideline from the American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and American Society of Clinical Oncology. *Arch Pathol Lab Med* **141**:625–657.

40. Lindeman NI, Cagle PT, Aisner DL, Arcila ME, Beasley MB, Bernicker EH, Colasacco C, Dacic S, Hirsch FR, Kerr K, Kwiatkowski DJ, Ladanyi M, Nowak JA, Sholl L, Temple-Smolkin

R, **Solomon B**, **Souter LH**, **Thunnissen E**, **Tsao MS**, **Ventura CB**, **Wynes MW**, **Yatabe Y**. 2018. Updated molecular testing guideline for the selection of lung cancer patients for treatment with targeted tyrosine kinase inhibitors: guideline from the College of American Pathologists, the International Association for the Study of Lung Cancer, and the Association for Molecular Pathology. *Arch Pathol Lab Med* **142**:321–346.

41. AMP, Association for Molecular Pathology. 2023. Practice guidelines. https://www.amp.org/clinical-practice/practice-guidelines. Accessed 5 March 2022.

42. Vege S, **Gannett MS**, **Delaney M**. 2020. *Introduction to Molecular Immunohematology*. AABB Press, Bethesda, MD.

43. Oxford English Dictionary. 2023. Supply chain. https://www.oed.com. Accessed 23 March 2022.

44. CFI Team. 2023. Supply chain. https://corporatefinanceinstitute.com/resources/management/supply-chain/. Accessed 10 March 2022.

45. Mahmoodi F, **Blutinger E**, **Echazú L**, **Nocetti D**. 2021. COVID-19 and the health care supply chain: impacts and lessons learned. *CSMP's Supply Chain Quarterly*. https://www.supplychainquarterly.com/articles/4417-covid-19-and-the-health-care-supply-chain-impacts-and-lessons-learned. Accessed 12 March 2022.

46. Dobrzykowski D. 2020. COVID-19 & supply chain management (video). University of Arkansas, Walton College. https://walton.uark.edu/initiatives/supply-chain-research/video-posts/covid-19-and-supply-chain-management.php. Accessed 20 October 2023.

47. Merriam-Webster Online Dictionary. 2023. Stewardship. merriam-webster.com/. Accessed 27 February 2023.

48. Hallworth MJ. 2011. The '70% claim': what is the evidence base? *Ann Clin Biochem* **48**:487–488.

49. Forsman RW. 2002. The value of the laboratory professional in the continuum of care. *Clin Leadersh Manag Rev* **16**:370–373.

50. American Hospital Association. 2013. Appropriate use of medical resources. https://www.aha.org/system/files/content/13/appropusewhiteppr.pdf. Accessed 31 March 2023.

51. Rawson TM, **Wilson RC**, **O'Hare D**, **Herrero P**, **Kambugu A**, **Lamorde M**, **Ellington M**, **Georgiou P**, **Cass A**, **Hope WW**, **Holmes AH**. 2021. Optimizing antimicrobial use: challenges, advances and opportunities. *Nat Rev Microbiol* **19**:747–758.

52. Eaton KP, **Levy K**, **Soong C**, **Pahwa AK**, **Petrilli C**, **Ziemba JB**, **Cho HJ**, **Alban R**, **Blanck JF**, **Parsons AS**. 2017. Evidence-based guidelines to eliminate repetitive laboratory testing. *JAMA Intern Med* **177**:1833–1839.

53. Baird G. 2014. The laboratory test utilization management toolbox. *Biochem Med (Zagreb)* **24**:223–234.

54. ABIM Foundation. 2023. Choosing Wisely: a watershed moment in health care. https://www.choosingwisely.org. Accessed 31 March 2023.

55. Dickerson JA, **Fletcher AH**, **Procop G**, **Keren DF**, **Singh IR**, **Garcia JJ**, **Carpenter RB**, **Miles J**, **Jackson B**, **Astion ML**. 2017. Transfusion laboratory utilization review into laboratory stewardship: Guidelines by PLUGS National Committee for Laboratory Stewardship. *J Appl Lab Med* **2**:259–268.

56. Procop GW, **Keating C**, **Stagno P**, **Kottke-Marchant K**, **Partin M**, **Tuttle R**, **Wyllie R**. 2015. Reducing duplicate testing: a comparison of two clinical decision support tools. *Am J Clin Pathol* **143**:623–626.

57. Procop GW, **Yerian LM**, **Wyllie R**, **Harrison AM**, **Kottke-Marchant K**. 2014. Duplicate laboratory test reduction using a clinical decision support tool. *Am J Clin Pathol* **141**:718–723.

58. Miller CE, **Krautscheid P**, **Baldwin EE**, **Tvrdik T**, **Openshaw AS**, **Hart K**, **Lagrave D**. 2014. Genetic counselor review of genetic test orders in a reference laboratory reduces unnecessary testing. *Am J Med Genet A* **164A**:1094–1101.

59. Greenblatt MB, **Nowak JA**, **Quade CC**, **Tanasijevic M**, **Lindeman N**, **Jarolim P**. 2015. Impact of a prospective review program for reference laboratory testing requests. *Am J Clin Pathol* **143**:627–634.

60. MacMillan D, **Lewandrowski E**, **Lewandrowski K**. 2004. An analysis of reference laboratory (send out) testing: an 8-year experience in a large academic medical center. *Clin Leadersh Manag Rev* **18**:216–219.

61. Verna R, **Velazquez AB**, **Laposata M**. 2019. Reducing diagnostic errors worldwide through diagnostic management teams. *Ann Lab Med* **39**:121–124.

62. Plebani M, **Laposata M**, **Lippi G**. 2019. A manifesto for the future of laboratory medicine professionals. *Clin Chim Acta* **489**:49–52.

63. US Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research. 2020. Revised recommendations for reducing the risk of human immunodeficiency virus transmission by blood and blood products. Guidance for industry. https://www.fda.gov/media/92490/download. Accessed 20 October 2023.

64. Rai S. 2022. Red Cross declares first national blood crisis in US. *The Hill*. 11 January 2022. https://thehill.com/policy/healthcare/public-global-health/589152-red-cross-declares-first-national-blood-crisis/. Accessed 4 March 2022.

65. Rai S. 2022. Doctors, nurses, hospitals warn blood shortage could jeopardize ability to meet patients' needs. *The Hill*. 27 January 2022. https://thehill.com/policy/healthcare/public-global-health/591631-doctors-nurses-hospitals-warn-blood-shortage-could/. Accessed 4 March 2022.

66. AABB. 2022. Oklahoma legislation offers tax credit to businesses that host blood drives. https://www.aabb.org/news-resources/news/article/2021/08/17/oklahoma-legislation-offers-tax-credit-to-businesses-that-host-blood-drives. Accessed 4 March 2022.

67. Anderson RE. 2021. Before COVID-19, outlier medical malpractice verdicts were rising—what's next? American College of Cardiology, The Doctors Company. https://www.acc.org/Membership/Join-Us/Benefits/Additional-Member-Only-Benefits/ACC-and-The-Doctors-Company/The-Doctors-Company-Updates/2021/04/06/17/38/Before-COVID-19-Outlier-Medical-Malpractice-Verdicts-Were-Rising. Accessed 3 March 2022.

68. White R. 2021. Malpractice claims from the COVID-19 pandemic: more questions than answers. American College of Cardiology, The Doctors Company. https://www.acc.org/Membership/Join-Us/Benefits/Additional-Member-Only-Benefits/ACC-and-The-Doctors-Company/The-Doctors-Company-Updates/2021/06/08/14/04/Malpractice-Claims-from-the-COVID-19-Pandemic-More-Questions-Than-Answers. Accessed 24 March 2022.

69. Hickey K. 2022. The PREP Act and COVID-19, part 1: Statutory authority to limit liability for medical countermeasures. Congressional Research Service, Legal Sidebar. https://crsreports.congress.gov/product/pdf/LSB/LSB10443. Accessed 12 March 2022.

70. McCoy CP, **Halvorsen AJ**, **Loftus CG**, **McDonald FS**, **Oxentenko AS**. 2011. Effect of 16-hour duty periods on patient care and resident education. *Mayo Clin Proc* **86**:192–196.

71. Zhang Z, **Krauthamer AV**, **Rosenkrantz AB**. 2018. The media response to the ACGME's 2017 relaxed resident duty-hour restrictions. *J Am Coll Radiol* **15**(3 Pt A):452–457.

72. Busireddy KR, **Miller JA**, **Ellison K**, **Ren V**, **Qayyum R**, **Panda M**. 2017. Efficacy of interventions to reduce resident physician burnout: a systematic review. *J Grad Med Educ* **9**:294–301.

73. Accreditation Council for Graduate Medical Education. 2023. Improving physician well-being, restoring meaning in medicine. https://www.acgme.org/meetings-and-educational-activities/physician-well-being/. Accessed 15 March 2022.

74. Dedeilia A, **Sotiropoulos MG**, **Hanrahan JG**, **Janga D**, **Dedeilias P**, **Sideris M**. 2020. Medical and surgical education challenges and innovations in the COVID-19 era: a systematic review. *In Vivo* **34**:1603–1611.

75. Murphy B. 2020. COVID-19: states call on early medical school grads to bolster workforce. AMA. https://www.ama-assn.org/education/changemeded-initiative/covid-19-states-call-early-medical-school-grads-bolster-workforce. Accessed 14 March 2022.

76. Columbia University Medical Center. 2020. To increase physician ranks, Columbia students will graduate early. https://www.cuimc.columbia.edu/news/increase-physician-ranks-columbia-medical-students-will-graduate-early-join. Accessed 14 March 2022.

77. Learn at ACGME. 2023. Well-being in the time of COVID-19. https://dl.acgme.org/pages/well-being-in-the-time-of-covid-19. Accessed 14 March 2022.

78. AAMC. 2023. Medical student well-being. https://students-residents.aamc.org/medical-student-well-being/medical-student-well-being. Accessed 20 October 2023.

79. AMA. 2023. Medical student well-being [search]. https://www.ama-assn.org/topics/medical-student-well-being. Accessed 20 October 2023.

80. ACGME. 2023. Learn at ACGME: Well-being. https://dl.acgme.org/pages/well-being-tools-resources. Accessed 20 October 2023.

4

The Changing Healthcare Environment

Steven M. Armstrong and Sandra L. Lamm

Introduction

Changing Provider Payment Models
Overview of Reimbursement Methods • Types of Managed Care Organizations • Managed Care and the Clinical Laboratory

Impact of Healthcare Reform

Patient Protection and Affordable Care Act

Payment Reform and Provider Reimbursement Strategies
Medicare Shared Savings Program • Value-Based Purchasing (VBP) • Other Payment Reforms • Hospitals and Laboratories: Concerns in Healthcare Reform

The Changing Legal Environment
HIPAA • False Claims Act

Technological Advances
Changing Testing Modalities • Pathology Informatics • Meaningful and Relevant Information • Impact of Bioinformatics on Pathology

Direct Consumer Access
Direct Access Testing • Direct-to-Consumer Testing

Consolidation in the Healthcare Industry
Consolidation of Practices • Integrated Delivery Systems • Internal Consolidation in Hospital Laboratories • Regional Integrated Laboratory Networks

Strategies for Future Success
Strategic Redesign • Supply Chain • Laboratory Design • Developing System-Wide Thinking and a Common Culture • Training Adequate, High-Quality Laboratory Professionals for the Future Workforce • Pathologist Shortage • Moving from Top-Down Management to Bottom-Up Customer Focus • Evidence-Based Medicine

SUMMARY

KEY POINTS

GLOSSARY

REFERENCES

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch4.

OBJECTIVES

To provide an overview of healthcare reimbursement models

To provide an overview of healthcare reform

To provide an overview of healthcare payment reform, including value-based purchasing

To understand the impact of healthcare reforms on hospitals and laboratories

To provide an overview of legal issues in the healthcare environment

To provide an outline of how consumer-driven medicine is changing laboratory testing models

To describe the impact new technologies are having on the hospital laboratory

To provide an outline of future changes that will impact laboratory service delivery

> *When obstacles arise, you change your direction to reach your goal, you do not change your decision to get there.*
>
> Zig Ziglar

THE CLINICAL LABORATORY HAS BEEN IMPACTED by a changing healthcare environment from both a reimbursement and legislative standpoint for quite some time. Starting in 1982, the Tax, Equity, Fiscal Responsibility Act (TEFRA) mandated prospective reimbursement for inpatient services rendered to Medicare beneficiaries, subsequently implemented under diagnosis-related groups (DRGs). The Deficit Reduction Act (DEFRA) of 1984 authorized the Medicare Clinical Laboratory Fee Schedule (CLFS) and mandated that the laboratory performing the outpatient testing, not the physician who ordered the testing, bill Medicare for the services directly.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) further impacted the environment. Then, in 1989, the Omnibus Reconciliation Act (OBRA) was passed and included legislation that prevented physicians from creating "shell laboratories" that contracted out the majority of testing and marked them up for direct billing. Laboratories were required to perform at least 70% of all testing on-site to be able to bill for referred testing (1). The Stark Law prohibited physicians with ownership in a laboratory from referring testing under self-referral legislation.

It is with this background that the clinical laboratory faces the current complexity and dynamism in the healthcare environment. Current focus has shifted to a reimbursement model that emphasizes quality over quantity while controlling costs. Significant health reforms and legislative actions continue to be implemented and will affect the clinical laboratory. The role of the clinical laboratory is evolving to include alternative health services delivery modalities due to technological advances. These changes will require a strategic rethink of the clinical laboratory's role in the healthcare environment as well as changes in the operations of the laboratory, providing laboratory managers both challenges and opportunities as the U.S. healthcare system continues its own evolution.

Changing Provider Payment Models

Overview of Reimbursement Methods

In healthcare, reimbursement refers to the payment given to healthcare providers for healthcare services. Provider payment methods typically have three components: the unit of the payment, the time frame of the payment (prospective or retrospective), and the degree of exposure to financial risk for the provider and payor (2). The unit of payment can be aggregate or disaggregate. An aggregate payment is a fixed payment to cover all services rendered by a healthcare provider to a specified population during a specified period of time. A disaggregate payment is a payment for a specific service, such as a laboratory test. Payment methods can also span the continuum between aggregate and disaggregate, such as a predetermined payment for services rendered per case to treat a specific DRG episode (3). A retrospective payment means the payment for treatment is determined after the service has been rendered. Fee-for-service (FFS) payments are an example of retrospective payments. A prospective payment is a payment that is determined before services are rendered. Case-based payments and per-diem payments are examples of prospective payments. The financial risk is usually higher for healthcare payors for retrospective and disaggregate payment models, while prospective and aggregate payment models carry more financial risk for healthcare providers (4). See chapters 31 through 36 of this volume for more detailed information on coding, billing, and reimbursement for healthcare services.

Following are the major reimbursement methodologies and their degrees of risk.

Fee-for-service (FFS). FFS, also known as an indemnity plan, is a disaggregate reimbursement methodology. The three types of FFS methods are cost-based reimbursements, charge-based reimbursements, and prospective payment systems (PPSs).

Cost-based reimbursement. In this retrospective reimbursement model, the health services payor will reimburse the health services provider for the costs of providing care to the payor's subscribers. This is a relatively low-risk method for health services providers, as cost-based reimbursement will typically cover the provider's costs.

Charge-based reimbursement. Also a retrospective reimbursement model, in charge-based reimbursement the health services payor will reimburse the provider based on the provider's charges, usually according to a listing of provider-supplied prices called a chargemaster. Charge-based reimbursements are also low risk for health services providers, but a rather high risk for payors of health services. Relatively few payors will pay the full amount of charges. Large health services payors such as managed care organizations (MCOs) or traditional insurance companies can use their leverage to negotiate discounts of the charges. Even self-pay patients often receive discounts, especially if they are low-income.

Prospective payment system (PPS). Initiated by the Centers for Medicare and Medicaid Services (CMS) in 1983 as part of the Social Security Amendments Act of 1983, PPS is a type of FFS where Medicare pays a predetermined amount to reimburse acute-care inpatient hospitals, home health agencies, hospice, hospital outpatient, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term-care hospitals, and skilled nursing facilities. These payments, determined by CMS, are not tied to costs or charges and constitute what is the expected cost of the healthcare service. There are four common payment units: payments per procedure, per diagnosis, per diem, and bundled, or global, payments. A bundled payment is a payment per episode of care that covers all the health services provided by all the health services providers. The risk to the health services provider can vary based on their proportion of Medicare patients.

Capitation. Capitation is an agreement in which a provider is paid a predetermined amount per member per month (PMPM) in exchange for providing services included in the rate. The rates are typically adjusted by age and sex and are adjusted according to population groups: commercial, industrial, prison, and Medicare. Rates should all differ based on actuarial data. Enrollment guarantees assure the provider that until the targeted membership rates are reached, the provider will receive FFS payments. Capitated payments are made prospectively to the provider at the beginning of the month for the total members, prior to any utilization or actual services rendered. Adjustments are made the following month based on change in membership. Since the costs for the services

rendered may exceed the capitation payment, the provider is at risk. To calculate PMPM:

$$\frac{\textit{Total revenue or expense or utilization units for the period}}{\textit{Number of member months for same period of time}} = \text{PMPM}$$

To calculate member months in a given period of time: (average number of members for each month in a given period) × (number of months in period) = member months for period.

Contract capitation is based on experience. There are three types of payments:

1. Capitation is paid based on qualifying member types rather than on a random patient population. The provider is only at risk for the costs associated with a referral and not for the number of referrals.
2. Global fees are paid for an entire episode of care.
3. Monthly fees are paid for a period of time and a specific condition.

Noncovered services. Services that are not covered need to be identified during contract negotiation to establish the method for billing and payment. In the managed-care environment, patients cannot be billed for services unless defined by the policy. Having the patient sign a waiver of liability prior to services ensures that the patient agrees to accept financial responsibility for the noncovered service and, according to the insurer's policies, allows the provider to then bill their usual, customary, and reasonable (UCR) amounts to the patient.

Traditionally, healthcare services were reimbursed using the FFS model. This payment model encourages supplier-induced demand for healthcare services, as healthcare providers are financially incentivized to provide high levels of care. Third-party payors, such as insurance companies, may implement various modifications of FFS to control costs. The types of FFS cost controls can include:

- *Fee schedules*: A list of the predetermined average or maximum fees, called the allowable fees, that the health services payor allows for the listed health services. The health services are usually defined by Current Procedural Technology (CPT) code sets.
- *Discounted FFS payments*: Reduced fees negotiated by a third-party payor for the payor's members. The discounted FFS payments are based on past claims and customary amounts based on geographical region.

However, while FFS cost controls may reduce healthcare costs, they still do not address the quality or efficacy of the services.

Managed care. Managed care models were designed to allow third-party payors to manage both the costs and outcomes of healthcare. MCOs encourage healthcare providers and patients to reduce costs and increase quality by:

- Using financial incentives to encourage physicians and patients to choose less costly forms of healthcare
- Reviewing the medical necessity of healthcare services and limiting payment to those services considered necessary
- Requiring preauthorization for inpatient admissions
- Limiting inpatient lengths of stay
- Requiring precertification for certain procedures, including procedures, tests, etc.
- Negotiating pricing with healthcare providers and preferred provider networks
- Applying proactive management of high-cost health care conditions
- Reducing healthcare fragmentation by having a singular primary care provider (4)

Types of Managed Care Organizations

MCOs use various provider network models with varying degrees of MCO control over patient and provider behavior.

Health maintenance organizations (HMOs). HMOs are the most controlling of the MCO models. HMO subscribers are typically limited to nonemergent care from in-network contracted healthcare providers. The HMO subscriber must also select a primary care physician (PCP) who serves as a healthcare gatekeeper. There are two main forms of HMOs, the group or staff model and the independent practice association (IPA). In the group model, a group of independent physicians contracts exclusively with the MCO. In the staff model, the physicians are employees of the MCO. In an IPA HMO, the physicians have a nonexclusive contract with the MCO and may treat other patients in addition to the contracted HMO subscribers.

History of HMOs. In an effort to control healthcare costs and increase the number of HMOs, the Health Maintenance Organization Act was passed in 1973. It had a number of provisions to promote the creation of HMOs, such as:

- Federal grants and contracts for public or private nonprofit organizations to determine the feasibility, planning, and implementation of projects to start or expand an HMO.

- Removing state restrictions on HMOs if the HMOs were federally certified. To be federally certified an HMO must:
  - Use a fixed community rating system for prepaid enrollment fees that does not consider the medical history of the subscriber or subscriber's family.
  - Cover certain basic health services such as:
    - Physician services including consulting and referral services
    - Inpatient and outpatient hospital care
    - Short-term (<20 visits) outpatient mental health services for evaluation and crisis interventions
    - Medical treatment for substance abuse
    - Diagnostic laboratory testing
    - Diagnostic and therapeutic radiological services
    - Home health services
    - Preventative care services to include family planning, infertility treatments, pediatric preventative dental services, pediatric eye exams if needed to evaluate for vision correction
  - Cover some supplemental health care services if they are available and the HMO member pays a nominal fee in addition to the HMO enrollment fees, e.g.:
    - Intermediate and long-term care
    - Non-basic health services; vision, dental, and mental health services
    - Long-term rehabilitative services
  - Ensure that basic and supplementary services (if enrolled) are available and accessible 24/7
  - Have adequate provider networks
  - Have an open enrollment period and may not refuse to enroll any member due to health status
  - Have a quality assurance program
  - Meet financial stability standards
  - Have an enrollee grievance process
  - Have consumer participation in the HMO policy-making body
  - Have equitable representation of medically underserved populations on the HMO policy-making body
- The "dual choice" provision. Employers with more than 25 employees were required to offer an HMO plan if a traditional insurance plan was already offered and the HMO met the requirements for a federally qualified HMO (5).

Although many of the requirements to become a federally qualified HMO were more burdensome than those required of traditional insurance plans, the HMO Act of 1973 allowed HMO plans to have a greater presence in employment-based insurance plans.

Table 4.1 Comparison of HMO and PPO models

Feature	HMO	PPO
Specialist care	Needs authorization from PCP to see an in-network specialist	No authorization needed to see a specialist
Allowable providers	Must stay in-network for nonemergent care	Can see an out of network provider
Cost of coverage	Lower premiums	Higher premiums

Preferred provider organizations (PPOs). PPOs are the least controlling of the MCOs. In a PPO, the MCO contracts with a network of health services providers for discounted rates for health services (6). PPO subscribers have lower costs if they use health services providers in the "preferred" network, although, unlike an HMO, subscribers can still seek care outside the network. Table 4.1 compares the HMO and PPO models.

PPOs came into being after the increase in HMOs following the Health Maintenance Act of 1973. They are attractive to both enrollees and MCOs. Enrollees can save money by choosing a preferred provider, yet still have the option to choose another health services provider, while MCOs can control costs through discounted fees. PPOs are currently the most common type of employment-based health insurance; a 2020 survey of private and non-federal employers found that 47% of covered employees were enrolled in a PPO compared to 13% who were enrolled in an HMO (7). Additional MCO models include the following.

Administrative services only (ASO). An insurance carrier or independent organization handles the administration of claims and benefits for a fee for self-insured groups.

Exclusive provider organization (EPO). Similar to an HMO, the enrollee is limited to nonemergent care from in-network contracted healthcare providers. Unlike an HMO, the enrollee does not need to choose a PCP or get a referral to see a specialist.

Integrated service network (ISN). Specialty networks have developed to provide coverage for a geographic area for care specific to their specialty (e.g., mental health services).

Laboratory services organization (LSO). A laboratory management group that administers contracts for a group of laboratories.

Management services organization (MSO). An organization that administers organizational and practice management for physician providers.

Physician hospital organization (PHO). An organization acting as a joint venture between a hospital and its medical staff to gain bargaining power with HMOs and PPOs or directly with EPOs.

Point-of-service (POS) plans. A POS model includes aspects of both an HMO and PPO. Enrollees must choose a PCP and get a referral from their PCP to see a specialist. However, they can choose to use in-network providers (at a lower cost) or seek treatment at an out-of-network provider.

Managed Care and the Clinical Laboratory

The rise of managed care has had a significant effect on clinical laboratories. The focus of managed care is on reducing utilization of unnecessary healthcare services, including diagnostic testing. Additionally, shorter lengths of stay are encouraged for inpatient care, and when possible, care is shifted to an outpatient setting. Therefore, hospital-based clinical laboratories have seen a reduction in their proportion of clinical laboratory testing volume, while commercial reference laboratories have increased their market shares (8).

Impact of Healthcare Reform

Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act (PPACA), signed into law in March 2010, enacted comprehensive reform to health insurance by holding insurance companies more accountable in an effort to lower healthcare costs, guarantee more healthcare choice, enhance the quality of care for all Americans, and increase access to care by providing small businesses with a tax credit to provide coverage. The PPACA had a number of market reforms, consumer protections, and provisions to increase access to care, improve healthcare quality, and lower costs that were implemented on the timeline summarized in Table 4.2.

The PPACA has seen a number of legal challenges since its inception, including three cases before the Supreme Court. While some significant portions of the PPACA have been invalidated, the law as a whole is still extant. Two of the stated goals of the PPACA are to "Make affordable health insurance available to more people" and to "Expand" the Medicaid program to cover all adults with income below 138% of the FPL" (9). Data reported from the Department of Health and Human Services (HHS) show that in 2021:

- There have been reductions in the uninsured rate in every state since the start of the PPACA's coverage expansions.

Table 4.2 PPACA implementation timeline

Market reforms, consumer protections, and provisions to increase access to care:	Improve healthcare quality and lower costs
2010	
• Requires the Department of Health and Human Services (HHS) to develop an internet website, www.healthcare.gov, where consumers can compare health insurance coverage options and pick the policy and coverage that works best. • Requires insurance companies that plan to significantly raise their insurance premiums to submit justification for the raises to state or federal governments for review. The review results must be accessible to the public and can be found at https://ratereview.healthcare.gov/ (accessed 22 May 2022). • Provides consumers with an avenue to appeal coverage determinations or claims, adding an external review process. • Funds state grants to establish consumer assistance programs to help navigate the private insurance system. • Provides small-business (<25 employees) tax credits of up to 50% of the costs the business pays towards employee premiums. • Requires individual and group insurance plans that offer dependent coverage to allow parents to keep their married or unmarried children on their plans up until age 26. • Allows certain insurance plans to be "grandfathered," allowing consumers to keep their current plans if they wish. • Allows employers to offer individual health reimbursement arrangements (HRAs), if certain conditions are met, instead of traditional group plans. • Parity in mental health and substance abuse treatment. The PPACA extends the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) to individual plans.	• Authorized the creation of the Patient-Centered Outcomes Research (PCOR) Trust Fund, funded in part by an assessment on private insurance companies. This fund finances the Patient-Centered Outcomes Research Institute (PCORI), which has the mandate to "improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers make better-informed health decisions" (11). • Authorized creation of the Independent Payment Advisory Board (IPBA). The IPBA was tasked with slowing the growth of Medicare spending by making expert saving recommendations if Medicare costs exceeded growth targets. No members were appointed to the Board and the authorization was repealed in the Protecting Seniors Access to Medicare Act of 2017.

(continued)

Table 4.2 *(continued)*

Market reforms, consumer protections, and provisions to increase access to care:	Improve healthcare quality and lower costs

• Patient bill of rights. Provides a number of consumer protections including:
  • Prevents insurance companies from denying insurance coverage on children under 19 based on preexisting conditions.
  • Prevents insurance companies from rescinding coverage based on unintentional mistakes on the insurance application.
  • Restricts annual limits on coverage.
  • Bans lifetime limits on coverage.
  • Allows consumers to choose their primary care provider from a provider's network
  • No need for a referral for OB/GYN visits.
  • No need for a referral to seek emergency care outside of the plan's network.
• Requires insurance companies to cover certain preventative services at no cost to plan holders.
• Requires nonprofit hospitals to conduct community needs assessments every 3 years or face a $50,000 fine per year.
• Provides increased funding for construction or expansion of community health centers.
• Establishes the National Health Care Workforce Commission.
• Created the temporary Early Retiree Reinsurance Program (ERRP) that reimbursed employment-based insurance plans for some of the health benefit costs for employees and their spouses who retire before they qualify for Medicare. This program ended in 2014.
• Created the Pre-existing Condition Insurance Plan that provided health insurance to people who were uninsured for at least 6 months, had a preexisting condition, and were denied coverage by a private insurance company. This plan ended in 2014 when everyone had access to plans on the health insurance marketplaces.	

2011	
• Requires insurance companies to spend at least 80 to 85% of premium dollars on medical care and healthcare quality improvement (medical loss) instead of administrative costs. Insurance companies that do not meet this standard must issue a rebate to their customers starting in 2012. • Closing the Medicare "doughnut hole": seniors who reach the Medicare Part D coverage gap will receive a 50% discount from drug manufacturers for brand-name prescriptions and also begins federal subsidies for generic drugs. Federal subsidies for brand-name drugs will start in 2013. Further reductions in coinsurance amounts will continue until the coverage gap is closed. • The Community First Choice allows states to offer home and community-based services to disabled individuals, rather than institutional care in long-term care (LTC) and intermediate-care (ICF) nursing facilities. • Provides payments for primary care residency programs and establishes Teaching Health Centers. • Redistributes vacant training positions and promotes training in outpatient healthcare facilities to increase the number of Graduate Medical Education (GME) positions. • Provides a temporary 10% Medicare incentive payment for primary care services. Provides a 10% Medicare bonus payment to general surgeons practicing in health professional shortage areas. • Requires coverage for annual wellness visits and personalized prevention plans for Medicare beneficiaries. • Increases state Medicaid payments to primary care physicians to no less than 100% of the Medicare payment rate for 2013 and 2014. These payments were funded by the federal government. • For states that offer Medicaid coverage for all recommended preventative care, provides funding for a 1% increase in federal matching payments for preventative care if there are no cost-sharing payments. • States will receive 2 more years of Children's Health Insurance Plan (CHIP) funding for coverage for children not eligible for Medicaid.	• Requires the secretary of HHS to develop a national quality strategy. • Creates the Hospital-Acquired Conditions (HAC) Reduction Program. Hospitals that rank in the lowest quartile based on their HAC score are penalized with a 1% reduction in total Medicare reimbursement. • Authorizes the creation of the Center for Medicare & Medicaid Innovation (CMMI). The CMMI is tasked with designing and testing new reimbursement models to address the issues of rising costs, quality of care, and inefficient spending in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

Table 4.2 *(continued)*

Market reforms, consumer protections, and provisions to increase access to care:	Improve healthcare quality and lower costs
2012	
No additional reforms this year.	• Requires the collection and reporting of data on race, ethnicity, sex, primary language, and disability status and on underserved rural and frontier populations to reduce healthcare disparities. • Creates the Medicare Value-Based Purchasing Program. Hospitals reimbursed under Medicare's inpatient PPS will receive incentive payments based on the quality of care they provide as measured by a select set of quality and cost measures. • Creates the Hospital Readmissions Reduction Program (HRRP). Hospitals with excess unplanned readmissions within 30 days of discharge for certain conditions will have their total Medicare reimbursement reduced by a certain percentage. • Created the Community-based Care Transitions Program. This 5-year program tested models to improve care for high-risk Medicare beneficiaries as they transitioned from hospitals to other settings, with the goals of reducing hospital readmissions, testing sustainable funding streams for care transition services, maintaining or improving quality of care, and documenting measurable savings to the Medicare program. • Creates the Medicare Shared Savings Program (MSSP). The MSSP provides incentives for the creation of accountable care organizations (ACOs). These voluntary organizations are networks of health services providers that coordinate patient care and may receive bonus payments if spending for patients is lower than a cost target, often known as the total cost of care (TCoC) benchmark. The ACO must also meet certain quality goals. Per PPACA guidelines, an ACO must care for at least 5,000 Medicare beneficiaries for at least 3 years. As of 2019 the agreement period is 5 years.
2013	
No additional reforms this year.	• Requires disclosure of the financial relationships between physicians, hospitals, pharmacists, other providers, and manufacturers and distributors of covered drugs, devices, biologicals, and medical supplies. • Created the Bundled Payments for Care Improvement (BPCI) Initiative as part of CMMI.
2014	
• Creates the state-based American Health Benefit Exchanges and Small Business Health Options Program (SHOP) Exchanges where individuals and small businesses with less than 100 employees can obtain coverage. • States will receive matching funds for covering additional low-income individuals and families who previously were not eligible for coverage under Medicaid. Citizens who earn less than 133% of the poverty level are eligible to enroll in Medicaid. • Ban on annual limits for coverage of essential benefits. • Guaranteed availability of insurance regardless of health status. Health insurance may only use age, geographic area, family composition, and tobacco usage to set premium rates. • Ensures continued coverage for individuals participating in clinical trials. • Individual mandate. Specified that individuals must have "minimum essential coverage" or face a tax penalty. The Tax Cuts and Jobs Act of 2017 set the tax penalty to $0, essentially negating the individual mandate. • Provides premium subsidies and cost sharing subsidies to eligible people. • Establishes the employer mandate. Employers with at least 50 full-time employees must offer insurance to at least 95% of the full-time employees or face fines of $2,000 per full-time employee. This mandate was delayed until 2015 for businesses with more than 100 employees and until 2016 for businesses with 50 to 99 employees (10).	No additional reforms this year.

- A record 31 million Americans have health insurance either through the ACA Marketplace (11.3 million) or Medicaid expansion (18.8 million). An additional 1 million have insurance through the PPACA's Basic Health Program.
- Between 2010 and 2016, the number of uninsured non-elderly adults fell from 48.2 million to 28.2 million, a 41% decrease (10).

Examining the effects of Medicaid expansion under the PPACA, a review of 404 studies found mostly positive results for measures of healthcare quality and affordability (11).

Payment Reform and Provider Reimbursement Strategies

Payment reform is primarily driven by the trend toward "value-based purchasing" over the former "services-based purchasing" environment. The strategy to integrate quality performance with reimbursement incentives has migrated from theory to common practice.

Medicare Shared Savings Program

Under the Medicare Shared Savings Program (MSSP), providers of services and suppliers participating in an accountable care organization (ACO) will continue to receive traditional Medicare (FFS) payments. The ACO will also be eligible to receive a shared savings payment if the ACO meets the quality performance measures and demonstrated cost reductions under the performance-based payment methodology (12).

The MSSP rewards voluntary participation in ACOs to better coordinate care. Coordinated care increases the chances that patients, especially chronically ill patients, will receive the right care at the right time while avoiding unnecessary duplication of services and preventing medical errors. The goal of ACOs is to lower growth in healthcare costs while meeting performance standards for quality care. For ACOs entering agreement periods in 2022, the performance standards included the quality domains:

- Communication and care coordination
- Community/population health
- Effective clinical care
- Efficiency and cost reduction
- Patient safety
- Person and caregiver centered experience and outcomes (13)

ACOs are not only associated with Medicare beneficiaries. The National Association for ACOs reports that as of January 2022, there are 483 Medicare ACOs covering over 11 million Medicare beneficiaries. Over 1,200 other ACOs have contracted with Medicare, Medicaid, or commercial plans (14).

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). MACRA, also known as the "Permanent Doc Fix," replaced the sustainable growth rate (SGR), which was used to control Medicare spending on physicians, and replaced it with the Quality Payment Program (QPP). The QPP gives physicians two pathways to participate:

Merit-based incentive payment system (MIPS). The MIPS has four performance categories; quality, cost, promoting interoperability, and improvement activities. Physicians receive a score from 1 to 100 based on their self-reported performance in these categories. The performance score will be compared to a CMS-determined threshold, and a positive, neutral, or negative payment adjustment is made to the physician's Medicare Part B reimbursement for the corresponding year (currently 2 years following the year in which the performance score was generated).

Alternative payment model (APM). The APM gives additional incentives to provide high-quality and cost-efficient care. The different types of APMs can apply to a certain clinical condition, care episode, or population (15).

Value-Based Purchasing (VBP)

VBP is a strategy used by both public and private purchasers of healthcare and health insurance services to maximize benefits while maintaining lowest costs (16). VBP rewards health services providers for providing quality care. The approach identifies specific performance requirements for contractors, insurers, third-party administrators, and direct service providers, holding them accountable by invoking clear consequences for inferior performance. Federal VBP predated the PPACA, but the passage of the PPACA started the shift from reimbursements based on quantity of services to reimbursements based on the value of the care. There are five original VBP programs administered by CMS for Medicare beneficiaries:

End-Stage Renal Disease Quality Incentive Program (ESRD QIP). Medicare payments to dialysis facilities for the treatment of patients who are receiving dialysis can be reduced up to 2% based on the facility's poor performance on quality-of-care measures.

Hospital Value-Based Purchasing (VBP) Program. Medicare payments to hospitals under the Inpatient Prospective Payment System (IPPS) are adjusted

based on their performances on quality measures in the following domains:

- Mortality and complications
- Healthcare-associated infections
- Patient safety
- Patient experience
- Efficiency and cost reduction

The program withholds 2% of funding from participating hospitals. Funds from this reduction are then used to fund value-based incentive payments based on a hospital's performance on the quality measures.

Hospital Readmission Reduction Program (HRRP). The HRRP incentivizes hospitals to reduce avoidable readmissions by improving communications and coordination with caregivers when discharging patients. General acute care hospitals that have an excess readmission ratio (ERR), determined as Predicted hospital readmission rate / Expected hospital readmission rate, for each of the following populations—acute myocardial infarction (AMI), chronic obstructive pulmonary disease (COPD), heart failure (HF), pneumonia, coronary artery bypass graft (CABG) surgery, or elective primary total hip arthroplasty and/or total knee arthroplasty (THA/TKA)—will have their payments adjusted based on a weighted average of their ERR scores for all the indicated populations. The payment adjustment will determine the percentage of payment reduction to be applied to all discharges.

Value Modifier (VM) Program. The VM Program, also called the Physician Value-Based Modifier (PVBM), incentivized physician practices to provide high quality and low-cost care by adjusting payments to physicians reimbursed under the Medicare Physician Fee Schedule (PFS). Reimbursements were adjusted up or down based on a value modifier, which was derived from composite scores in quality and costs. The quality composite score was based on performance in as many as six quality domains for Medicare beneficiaries:

- Clinical process/effectiveness
- Patient and family engagement
- Population/public health
- Patient safety
- Care coordination
- Efficient use of healthcare resources

The cost composite score was based on performance in two cost domains for Medicare beneficiaries:

- Per capita costs for all attributed beneficiaries
- Per capita costs for beneficiaries with specific conditions

Based on comparing quality and cost scores to a peer group of practices, the practice was then rated as high, average, or low quality and cost, and reimbursement rates were adjusted accordingly. The VM program was phased out in January of 2019 and replaced by the Merit-based Incentive Payment System (MIPS).

Hospital Acquired Conditions (HAC) Reduction Program. The HAC Reduction Program incentivizes hospitals to improve patient safety to reduce HACs by implementing best practices. There are two measures used to determine payment adjustments. The first is a composite score, the Patient Safety and Adverse Events Composite (CMS PSI 90), calculated from Medicare FFS claims. The second measure is the Centers for Disease Control and Prevention National Healthcare Safety Network healthcare-associated infection (HAI) measures. The HAIs measured are central line-associated bloodstream infection (CLABSI), catheter-associated urinary tract infection (CAUTI), surgical site infection (SSI) (for colon and abdominal hysterectomy procedures), methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridioides difficile* infection (CDI).

General acute-care hospitals that score in the worst quartile have their payments reduced by 1%. The HAC reduction is applied after any adjustments from the hospital value-based purchasing and HRRP.

Other Payment Reforms

Middle Class Tax Relief and Job Creation Act of 2012. The PPACA had several payment reforms, including:

- Reducing the amount of annual increases in payments to hospitals in anticipation of increased numbers of insured patients and lower need for uncompensated care
- Reducing Medicaid disproportionate share hospital (DSH) payments in anticipation of Medicaid expansion (less indigent care)
- Reducing payments to Medicare Advantage plans and replacing the payments with an annual, fixed federal payment
- Switching to a value-based payment system (17)
- Changing the formula used to calculate the Medicare Clinical Laboratory Fee Schedule (CLFS)

The Middle Class Tax Relief and Job Creation Act of 2012 continued some of these reforms by:

- Extending the DSH payment reduction from the PPACA for an additional year
- Implementing a 2% cut to Medicare Part B CLFS laboratory test fee schedule (18)

The Protecting Access to Medicare Act of 2014 (PAMA). Although the main purpose of the PAMA was to prevent a significant cut in physician reimbursements, PAMA had several provisions that affected the clinical laboratory:

- A requirement for clinical laboratories to submit private payor rates for laboratory tests every 3 years
- Arguably flawed data used to set reimbursement rates
- Significant cuts in the CLFS (19)

In 2019, the Laboratory Access for Beneficiaries Act (LAB Act) was passed to mitigate and delay some of the provisions of PAMA. Further delays were included in the Coronavirus Aid, Relief and Economic Security (CARES) Act of 2020 and the Consolidated Appropriations Act of 2023.

Hospitals and Laboratories: Concerns in Healthcare Reform

Hospitals. The shift from FFS and volume-based measures to ACOs and quality-based measures will force hospitals to either cut costs or create new revenue streams to remain solvent. The following strategies may offer a more profitable operating margin:

- Focus on the entire continuum of care including admission, service, discharge planning, post-acute care, and follow-up.
- Align efforts of hospitals and physicians to schedule and have patients attend post-acute-care visits, as readmissions have a negative impact on the bottom line.
- Maintain a sound relationship with payors, benchmarking, and renegotiating managed-care contracts to eliminate underpayment for services, as 35% of hospital net revenues generally come from private insurers.
- Research opportunities for new service lines to increase market share with an improved revenue stream. At the same time, evaluate current service lines for opportunities to eliminate the hemorrhage from shrinking returns.
- Control costs of human resources by cross-training employees to cover in areas of short staffing as needed. Use metrics (such as "dollar per patient day") to monitor shifts and trends in the labor force.
- Partner with vendors to negotiate price controls that reduce supply costs and eliminate excess inventory using just-in-time supply delivery where it makes sense. Include physicians in the cost-conscious strategies for supplies.
- Improve operations in the emergency department (ED) and the operating room. Hospital EDs handle increasing numbers of uninsured patients daily that are probably eligible for a publicly funded program. Financial screening, at the point of entry, is crucial to ensuring reimbursement for services.
- Develop and implement chronic care programs for asthma, cardiovascular disease, diabetes, and hypertension. Collect data to mitigate costly chronic care issues before they become long-term health conditions.
- Evaluate benefits and savings from outsourcing services such as laundry, housekeeping, food, maintenance, and even nurse education.

Laboratories. Rampant changes in policy and purchasing and scientific developments are driving the transformation of the healthcare industry and are creating a major shift in dynamics, and the clinical laboratory industry must adapt. The primary drivers of the change include:

- Payment reform that is shifting away from FFS to value-based purchasing and risk contracting. The CLFS reimbursements are being reduced annually, and payors are putting payment caps on new diagnostic test pricing.
- Healthcare delivery reform based on providers' coordination of care and population management.
- Emerging era of personalized medicine with clinicians who need assistance in understanding and using molecular diagnostic laboratory testing and payors attempting to control molecular test utilization.

Healthcare reforms with an emphasis on value-based purchasing will require a paradigm shift in the clinical laboratory. Before, the laboratory was focused on operational efficiency. In the post–healthcare reform, value-based purchasing environment, the clinical lab will need to focus on clinical effectiveness.

Clinical effectiveness includes the right test at the right time with correct interpretation of that test to best inform the provider and guide patient management. Clinical effectiveness can be enhanced in a variety of ways, such as including clinical recommendations in test result reports and, for complex testing, providing interpretation consulting (20). These actions also help rebrand the clinical laboratory as a value-enhancing service. Other strategies that can add value to clinical laboratory services include:

- Implement an outreach program. This can create the infrastructure to provide coordinated care across a range of environments.

- Ensure that the laboratory has input in implementing electronic medical records (EMRs) and that laboratory data are available across a range of healthcare environments.
- Make sure laboratory services and information are accessible and convenient.
- Ensure the laboratory is involved in development and updating of computerized physician order entry (CPOE) with clinical decision support (CDS), testing algorithms, and clinical pathways.
- Align the laboratory's objectives with those of the health system.
- Be aware of competing laboratories (21).

The Changing Legal Environment

The healthcare legal environment is also facing significant changes, many arising from previous healthcare reform legislation. Following are some of the significant issues that hospitals, health systems, and clinical laboratories face.

HIPAA

Health Insurance Portability and Accountability Act (HIPAA) data breach violations are expected to increase as the interoperability of electronic health records (EHRs) expands to share data between IT networks (22). Medical devices can be connected to the internet or individual cell phones, leaving them vulnerable to HIPAA breach violations. Hacking, however, is the main cause of data breaches (23). The financial penalties for HIPAA violations can be quite severe, up to $1.5 million if the breach was found to be due to willful neglect and it was not corrected within 30 days.

False Claims Act

The False Claims Act (FCA) imposes liability upon anyone who knowingly submits false claims to the government. This includes false claims for Medicare or Medicaid payments. The PPACA significantly expanded the FCA by:

- Requiring physicians to report and return any Medicare or Medicaid overpayments to the government within 60 days of discovery of the overpayment. If this requirement is not met, the physician could be in violation of the FCA.
- Before the PPACA, intent to defraud the government and knowledge of the regulation had to be established to prosecute a violation of the Anti-Kickback Statute under the FCA. The PPACA removed the requirements of intent and knowledge.
- Eliminating the requirement that whistleblowers have to be the primary firsthand source of the violation.

The Physician Self-Referral Law, also known as the Stark Law, prohibits physicians from referring patients to receive "designated health services" from facilities in which the physician or an immediate family member has a financial interest. These designated health services include clinical laboratory services. The PPACA made the following changes to the Stark Law:

- Removed the whole-hospital exception. Previously, physicians were permitted to refer patients to a hospital the physician had a financial interest in if the financial interest was in the whole hospital.
- Required physicians to give written notice to patients disclosing their financial interest in the designated services provider.
- Required physicians to give written notice that the patient can seek designated services elsewhere if desired.
- Required a protocol for healthcare providers and suppliers to self-disclose potential violations of the Stark Law; this allows the secretary of HHS to reduce the penalties for self-disclosed violations.

Technological Advances

Patient care continues to evolve from inpatient settings to outpatient and at-home care. Point-of-care testing (POCT), including at-home testing, spurred by cost reduction opportunities, technological advances, and the SARS-CoV-2 (COVID-19) pandemic, has demonstrated considerable growth over the past few years (24). As laboratory testing technology advances in reliability, accuracy, portability, and reporting of POCT and at-home testing, basic laboratory testing will continue to move beyond the traditional clinical laboratory setting.

It is important to note that technology within the conventional laboratory has also continued to expand. The increased use of molecular testing platforms (e.g., immunohematology, microbiology), artificial intelligence, digital imaging, telepathology, and robotics are just some examples that will continue to become ubiquitous.

The constant evolution of laboratory testing methodologies and platforms does come with its own challenges. Successful clinical laboratory management involves more than being a good pathologist, researcher, or laboratorian. It also combines clinical expertise with business acumen as technology and the laboratory continue to advance and adapt within the modern healthcare environment. Therefore, it is imperative that laboratory leaders remain aware of current technology and trends, as well as those in development, to be successful.

Changing Testing Modalities

Laboratory testing has traditionally been perceived as a dichotomy regarding testing modalities. The division between manual and automated testing was a differentiator among laboratories (e.g., large versus small). However, embracing technological advances in the modern laboratory is no longer a luxury, but with continued workforce and financial pressures, has become a necessity. The laboratory of today, and the future, will continue to modernize through ongoing changes in testing platforms and expanded public availability.

Fast-occurring changes in microelectronics, cellular therapy, molecular biology, genomics, chemistry, imaging software, and miniaturization have become integrated into and now redefine the landscape of laboratory medicine (25). In addition, the continued expansion of robotics and automation, POCT, artificial intelligence, and "omics" data generation will continue to define further the future of laboratory medicine (26).

Pathology Informatics

Laboratory data provide an incredible amount of information for the clinical team to provide patient care. However, this vast amount of data has made it difficult for providers to decipher what is meaningful and relevant to their patients' care. Pathology informatics is a burgeoning aspect of pathology that uses complex patient data sets to help provide improved patient care and understanding of disease. As the complexity of laboratory data expands, it is necessary to monitor the usefulness of testing to provide disease diagnosis and monitoring.

Meaningful and Relevant Information

Managed care was not formed initially to focus on utilization control. The purpose was to keep track of the patient's medical record and steer the direction of care from treatment to prevention. This was next to impossible since the HMOs primarily handled claims and billing data. Integrated delivery networks evolved on the provider side in an attempt to gather more complete information about the patient. In response, hospitals and providers formed community health information networks to build a centralized database that would contain all the medical records for every patient in the community network. This thinking was correct because the goal was connectivity. Other attempts at data collection include data warehousing and the implementation of an EMR. Ultimately the ability to assemble the complete patient care and treatment experience in a single location will decrease medical errors, improve patient care, and fundamentally change the way healthcare is delivered (27).

Healthcare is changing throughout the world, with screening, diagnosis, and chronic disease management being redirected from the hospital environment to the physician providers and the patient. Improving the speed of getting test results to the clinical team and the patient allows for quicker interventions. Quicker interventions, at least in theory, lead to better disease management to improve care and reduce costs.

The laboratory's role in informatics. Laboratory test results are of limited use in the absence of supporting clinical information. Descriptive elements of clinical information include gender, race, sex at birth, age, occupation, health status, signs and symptoms, patient status, family and medical history, and social behavior. Fueled by a complex healthcare environment and an ever-expanding array of diagnostic procedures, the need for increased integration between clinical information and laboratory data has become vital. Genetic testing, in particular, requires that the test be performed as an adjunct to patient management and used in conjunction with the patient's clinical information. The trend toward evidence-based patient care while focusing on the patient will be challenging. The role of the laboratory in response to these challenges and opportunities will be to contribute medically relevant and value-added information to the future multidisciplinary approach to the management of the patient (28).

In determining value, laboratory information must be differentiated from laboratory data. If we only consider data, laboratories simply perform the right test on the right patient at the right time and format for the right price. The element that brings value to information is the ability to provide the right result referenced to the right ranges, with the right interpretations and consideration of the test limitations. The information may also include the right advice on how to use the test information with the right knowledge of the clinical context of the testing. For laboratory information to be of value, it must convey results in a manner that assists the provider in estimating the probability of disease and affects subsequent patient management decisions toward improving patient outcomes (29).

Improving clinical decisions through evidence-based laboratory medicine. Evidence-based medicine is fueled by the requirements for data collection and patient outcome information, cost containment, and consumer demand for the best in diagnostics and treatment (30). The value of clinical guidelines, care maps, and outcome measures as useful quality improvement tools is weighed against the service's clinical appropriateness, efficiency, and effectiveness. To demonstrate the impact of laboratory testing on an increasing number of clinical outcomes, laboratory professionals must be able to search electronic and paper sources for evidence; use analytical, statistical, and epidemiological knowledge; demonstrate critical thinking skills; and understand the strengths and weaknesses of the systematic review process.

Systematically finding, appraising, and using research findings as the foundation for clinical decision making is not always feasible. To make the best clinical decision for patients, laboratories serve as clinical consultants, and much effort has been placed on determining best practices for communicating laboratory results for diagnosis, treatment, and prognosis. Laboratorians should follow a quality-improvement approach that includes asking if the care is appropriate, efficient, and effective.

Clinical practice guidelines are statements developed to assist practitioners in general decisions about patient care, using specific clinical applications from prior experience and researched evidence. The care map is the critical pathway document (often formatted as a grid or algorithm) that maps care by a set of decision tree steps serving as a guideline in a structured healthcare process for the provision of care. Assessment of outcome reviews the initial care map and may improve the clinical guideline by eliminating bias in the research. Efficacy is the ability of a procedure or test to achieve the desired clinical purpose in a controlled setting with a controlled group of patients. Effective treatment is based on demonstrating the desired effect in a larger population, showing the value applied to the standard of care.

The application of evidence-based medicine research into daily clinical practice has challenges. There are significant differences between a patient's care and the practice which the evidence suggests is effective.

Impact of Bioinformatics on Pathology

Pathologists have long suspected that bioinformatics would turn their world upside down. As test results and clinical patient data merge, the previously clear distinction between the roles of anatomic and clinical pathologists blurs. Technology expansion requires that pathologists understand how molecular diagnostics bridge the gap between research and clinical care. Pathology is witnessing a gradual shift from cell morphology to the molecular structure and function of cells as an adjunct to the diagnostic process, including genomic and proteomic testing. As bioinformatics becomes a significant driving force in pathology, result reporting will steadily demand a larger share of the pathologist's daily routine. At the same time, bioinformatics raises difficult questions about the nature of disease. The concept behind bioinformatics is to study significant patterns in large data sets, not in individual biological entities. Pathologists must understand the stewardship of the resource that will become the foundation for bioinformatics in the clinical laboratory and at the same time also develop a comprehensive, well-organized clinical biorepository. The clinical laboratory must have expertise in handling large data sets, while the anatomic pathology laboratory must have a keen perspective and understanding of cellular biology (31).

Expansion of testing outside the clinical laboratory. Technological advances have allowed care providers to significantly increase the speed with which they receive clinical test results. Results are available in real time for many routine tests as the providers interact with the patient. In addition, technological advances have allowed the rapid growth of point-of-care and at-home, direct-to-patient testing. The available menu of at-home direct-to-consumer testing continues to expand rapidly, from traditional pregnancy testing and glucose monitoring to colorectal cancer screening, COVID-19 infection, and many more.

Point-of-care testing (POCT). Microelectronics, microfabrication, and microcomputerization have revolutionized how laboratory tests are performed. These technologies allow test results to be obtained in minutes or even seconds. POCT, or near-patient testing, has long been touted as the technology that would change patient management in the world of managed care. The most apparent benefit of POCT is decreased turnaround time (TAT). The premise that near-patient testing would radically change patient management under managed care has not been substantiated (25). Hausfater's research concluded that POCT had no significant impact on hospital length of stay (LOS) (32). Receiving rapid results does reflect the patient's status at a given time and improves pharmacological management. Some studies suggest that POCT can reduce the amount of time a patient stays in the ED, but at a significantly higher cost per test; however, little evidence supports POCT leading to improved outcomes (33). Table 4.3 lists the advan-

Table 4.3 Advantages and disadvantages of point-of-care testing[a]

Advantages	Disadvantages
Shortened turnaround time	Concerns for inaccuracy, lack of precision and performance Interfering substances Analyte ranges more narrow
Improved patient outcomes	Quality management and assurance practices poorly defined
Reduced preanalytic errors Requires smaller sample volume Elimination of sample degradation Eliminates specimen mislabeling	Potential for increased clinical errors Test quality is operator dependent Lack of password security
Self-contained, user-friendly instruments	Frequent lack of connectivity
Shortened critical-care stay	Increased costs over core lab
Handles variety of sample types: whole blood, urine, and saliva	
Potential applications: home health, rescue, and military operations	
Convenience for physicians	

[a] See reference 52.

tages and disadvantages of POCT. Research and development must carefully evaluate instrument limitations, especially for the critical-care setting (34). However, as technology evolves, and POCT becomes easier to perform, the differences traditionally demonstrated between POCT and laboratory testing continue to diminish.

Meanwhile, cost minimization strategies vacillate between pushing the testing back to the clinical laboratory, where cost-effective testing and accuracy can be maintained, versus POCT, where physicians can treat more quickly and, at least theoretically, reduce complications and overall organizational expenses. Following the development cycle of mobile computing devices (e.g., smartphones, smartwatches), personal computers, widely available high-speed internet access, and distributed computing, the use of POCT will continue to become ubiquitous in both healthcare and non-healthcare settings, including in the patient's home for monitoring for both chronic and acute conditions. While patient home monitoring of some chronic conditions is commonplace (e.g., diabetes), other more diverse conditions have also demonstrated the potential benefit of home monitoring (35).

Point-of-care testing and home healthcare. The U.S. population is living longer, and providing care for the elderly has significant implications for healthcare costs. The U.S. has more individuals 60 years old or older than citizens 15 years old or younger for the first time (36). In 2023, annual home health care costs are expected to exceed $143 billion (37). As the number of patient home care visits increases, it will be essential to assign disease management strategies to minimize costs. As a result, the home health market will increasingly rely on POCT and vital sign technology combined with patient management and information systems (38).

Telepathology. Since the introduction of the personal computer and the information age, the practice of pathology has been changing. Pathologists can now collaborate in real time over great distances by combining digital imaging, computers, and high-speed broadband digital networks. With the FDA approving the use of whole-slide imaging (WSI) digital pathology platforms, there are opportunities to be gained; however, many legal and regulatory obstacles remain (39). The cost of implementation of digital pathology is extensive, and when coupled with insufficient reimbursement, the demonstration of a positive return on investment is difficult (40). However, it is likely that as the shortage of pathologists persists across the U.S., the use of telepathology will become a necessity to provide pathology services to those in need, and the barriers to mass implementation will be addressed out of necessity.

Telepathology, especially with WSI, can become a significant part of a reference laboratory's marketing proposals. The service can be used to confirm the diagnosis made by a colleague, provide diagnostic assistance to less experienced pathologists, or provide clinical support where in-house pathology services are unavailable. Telepathology can also be used to link the pathologist with the surgical suite, where a discussion of relevance and details related to tissue or lesion margins is conveyed. Telepathology expands the ability of a pathology practice to provide services to multiple community hospitals and physician office laboratories. New Category III CPT codes for the technical costs of digitizing slides for diagnostic purposes were implemented by CMS in 2023; this will eventually help defray some of the cost of digital pathology and telepathology. Even without this financial support, at least part of the value of telepathology comes from its potential to break through geographic boundaries (41).

Direct Consumer Access

Technology-savvy healthcare consumers expect to visit a healthcare provider's website to schedule a visit, preregister for care, receive patient information instructions, review test results, view healthcare history, pay bills, and even access travel and parking directions. Healthcare facilities and their providers, whose focus is on providing a positive consumer experience via technology, have a strong competitive advantage. As a result, physician loyalty is typically increased when patients are no longer required to spend time dealing with service issues. Healthcare stakeholders benefit from increased productivity because the physicians have more time for direct patient care. Hospitals that provide the best customer service attract the best physicians, who attract more patients (42).

In addition to healthcare consumers embracing technology to improve their experiences, they also expect to use the technology themselves to improve their care. This has become even more evident when it comes to direct-to-consumer (DTC) testing. With DTC, laboratory testing has expanded to be more within the control of healthcare consumers, and this trend will continue.

Direct Access Testing

Direct access testing refers to laboratory testing performed at the patient's request as the consumer. Patients who utilize these services are motivated for different reasons:

- To confirm health or wellness as a result of seeing, reading, or family history
- To assess risk from exposure when lifestyle indicates the need
- To monitor the status of existing conditions
- To avoid a physician's office and/or laboratory visit

It is important for laboratory leaders to understand the motivational factors that drive consumer behavior regarding laboratory testing.

Direct-to-Consumer Testing

Consumers have three basic types of DTC testing: consumer-performed testing, at-home collection, and prescription-required at-home collection. The list of DTC testing continues to expand rapidly as all three testing types become the expectation as healthcare consumers become more engaged in their health. An updated list of available DTC testing can be found online (https://www.testing.com/at-home-testing, accessed 6 September 2023).

Consumer-performed. Consumer-performed testing is laboratory testing that the consumer can perform and interpret without a prescription. Consumer-performed testing includes routine glucose monitoring, drug testing, pregnancy testing, and many others. These tests have become commonplace and are sold over the counter (OTC) at retail stores and pharmacies across the U.S. During the COVID-19 pandemic, consumer-performed testing was expanded to include COVID-19 home test kits. As a result, consumers can quickly access their provider for additional testing and treatment options with these test results in hand. However, many of the results go unreported to care providers. For example, introducing at-home COVID-19 testing kits may have led to the underreporting of new cases (43).

At-home collections. At-home collection refers to the collection of testing material by the consumer without a prescription, but unlike consumer-performed testing, the testing and interpretation are completed at a laboratory. The most common example of this is DNA testing. For example, genetic marker testing kits may be obtained OTC and, once collected, sent for testing, interpretation, and reporting by the servicing laboratory. Consumers can then share their results and concerns with their care provider.

Prescription-required at-home collections. The differentiator between at-home collections and prescription-required at-home collections is the latter needs a provider's prescription. The necessary prescriptions may be obtained through telemedicine providers or in-person visits. This is a quickly growing area of testing that can provide consumers quick access to colorectal cancer screening, hepatitis testing, and many others.

The important aspect of all three testing modalities is that healthcare consumers are becoming more active in their care. While there are concerns regarding patients misdiagnosing, lack of follow-up care, result accuracy, confidentiality, overtesting, improper preparation, and unexpected emotional responses (see Table 4.4 for a more

Table 4.4 Potential risks of direct-to-consumer (DTC) testing[a]

Privacy	
	Data can be released to third parties
	Risk of data being compromised
	Cybersecurity vulnerabilities, ransomware
	Access and use by law enforcement
	Denial of insurance benefits
	Release of information on relatives who may not have consented
	Results not protected by laboratory regulations
Technical limitations	
	Sensitivity and specificity
	Accuracy and precision
	Different results with different methods
	Sample tracking, integrity tracking, lack of "chain of custody"
Cost	
	DTC not covered by insurance
	Some tests can be expensive
	Confirmatory follow-up can be costly
Clinical utility	
	Risk prediction versus disease diagnosis
	Marketing could overstate utility
	Lack of actionable information due to multiple factors that influence disease
Incorrect diagnosis	
	Unnecessary lifestyle changes, surgeries, or procedures
	Morbidity and mortality
	Influence on family planning decisions
Overutilization	
	Repeating test in hospital lab to confirm
	Unnecessary testing with higher false positives and negatives
	Increased burden on healthcare resources
Provider-patient relationship	
	Distrust if DTC test does not agree with provider plan of care
	Reconciliation of discrepant clinical and DTC results
Interpretation	
	Assistance with interpretation may not be available or provided by company
	Counselors may not be licensed, competent, or qualified
Emotional	
	Anxiety from test results
	Confusion about significance of results
Community	
	May locate unknown family members
	Disease communities/social identity may change if result interpretation is updated in the future
Clinical validity	
	Pretest probability
	Risk accuracy
	False positives and false negatives

[a] Reprinted with permission from reference 44.

extensive list), the fact remains that changes to traditional laboratory testing are going to continue (44). Therefore, successful organizations must find a way to integrate these testing modalities to enhance the patient experience.

Consolidation in the Healthcare Industry

Between 1992 and 1994, efforts to enact comprehensive, national healthcare reform failed miserably. Since then, driven by powerful economic forces and the fear of economic consequences, the industry has undergone significant restructuring. The healthcare industry has turned to mergers, acquisitions, joint ventures, and consolidation to fortify its position and protect market share. The effects of the consolidation have been felt in every market sector.

The primary goals of mergers, acquisitions, and consolidation are to grow business opportunities, create new lines of business that are not currently accessible, take advantage of cost synergies, or a combination of the three. While the three goals are also important regarding laboratory operations, the primary focus is usually on cost reduction through streamlining operations and incremental cost-per-test reductions through increasing testing volumes. While there are savings to be had, cost synergies are dependent on the automated testing platforms in use and cease to be linear after the testing volume reaches approximately 1 million annual tests. While increased volumes can reduce the cost per test, after approximately 1 million annual tests the organizational type, patient type and complexity, and laboratory organization create limits to additional savings (45).

For health system-based and large corporate laboratories, the use of a centralized testing model will continue to grow except for the most immediate laboratory testing results. When coupled with the growth of decentralized testing (e.g., POCT), the opportunities to streamline laboratory service delivery remain an effective cost reduction strategy that increases in volume can enhance. The seemingly dissonant expansion of both centralized and decentralized testing can harmonize when managed correctly. It is finding the balance that meets patient care and cost reduction goals that will maximize gains achieved from mergers and acquisitions (M&A) and consolidation strategies.

The increase in health system M&A has been consistently ongoing for over 2 decades. From 2015 to 2020 alone, the average number of mergers was nearly 50 per year. Even in 2021, during the COVID-19 pandemic, there were still 27 M&A during the first two quarters of the year (46). As smaller hospitals and hospital systems begin to merge into larger health systems, it is expected that the number of annual M&A will decrease; however, M&A will continue as larger systems continue to merge to form immense organizations.

Unfortunately, the M&A process among hospitals has led to a decrease in available inpatient beds across the U.S. From 1960 to 2018, there was a 44% reduction in inpatient beds from 1.6 million to 900,000 (47) despite an 85% increase in the U.S. population (152 million) from 1960 to 2020 (48). Obviously, inpatient population management has changed significantly over the years, but the fact remains that a shortage of inpatient beds became a significant issue during the COVID-19 pandemic and will need to be addressed in the future. The continued move from traditional inpatient to outpatient care further demonstrates the need for increased outpatient access to testing performed at centralized laboratories, POCT, or at home.

Consolidation of Practices

Physician practices have merged to become group practices and networks to increase efficiency. Sharing office space allows physician groups to expand their service area while eliminating the duplication of leased space expenses. As a result, solo practitioners are becoming virtually extinct as they become more cost-prohibitive. The same trend has occurred with pathology practices, as smaller groups have merged with or been absorbed by larger groups, sometimes funded by private equity investors or other large organizations.

MCOs have been acquired by larger firms to lower expenses and increase efficiency through economies of scale. As competition in the market decreases, employers and consumers fear deterioration in the quality of services and price increases more than the anticipated reductions from the efficiencies achieved (49). The maturing of the managed-care market contributed to consolidation among managed-care plans. Traditionally, managed-care penetration is most significant in large urban areas, and POS health plans are more successful in rural communities.

Integrated Delivery Systems

An integrated delivery system (IDS), also known as an integrated delivery network (IDN), is a legal structure formed by hospitals and physicians to share financial risk when collectively negotiating contracts for services with the IDS health system. Hospitals are encouraged to shift from treating populations in an episodic manner to comprehensive health management. Healthcare providers form IDSs to meet the needs of the payors, purchasers, and consumers. The ability to offer one-stop shopping with convenient access in a defined region allows providers to offer a seamless continuum of care from the primary care physician to tertiary services. The success of the IDS model has produced more than 1,100 active networks in the United States (50). The continued growth of the IDS model is expected to continue as non-integrated systems continue to search for efficient and economical solutions to providing the ever expanding healthcare need.

Internal Consolidation in Hospital Laboratories

Consolidation is a strategy whereby several hospital laboratories downsize individual facility laboratories and funnel most specimens into a centralized (also called a core) laboratory. This strategy achieves lower costs per test and improves the competitive position of the consolidated laboratory operation. The primary goals of internal laboratory consolidation include eliminating duplication of services and excess capacity, restructuring workflow, changing staff resources, and centralizing management. Another advantage of internal consolidation is increased test volumes, enabling the laboratory to bring more testing in-house, reducing referrals, lowering costs, and improving turnaround time (TAT). Laboratory consolidation offers the following benefits:

- Integration of clinical information across the healthcare continuum
- More economical delivery of services
- Management of the test cycle/production times
- Electronic links to the providers and consumers
- Provision of meaningful and relevant information for improved outcomes

Regional Integrated Laboratory Networks

Restructuring trends used in the consolidation process, such as downsizing, POCT, internal laboratory consolidation, and interdisciplinary team approaches, paved the way for regional network development and alliances among laboratories. Interestingly, reengineering efforts of the 1990s that were linked to continuous improvement proved more effective than downsizing or restructuring (51).

Reengineering limited to compliance, quality improvement, and cost containment produced some internal financial improvements but had little effect on innovation or long-term growth. The primary objective of regionalization is to develop a system of laboratories capable of providing services to a larger geographical area and positioning the laboratory system to compete for managed-care contracts (52). Regional networks were formed with core laboratories linked to multiple rapid-response and point-of-service sites. This type of system enables the aligned laboratories to market the combined strengths of the collective test menus, keeping more tests within the regional system and eliminating referrals outside the system. Operation and ownership of the laboratories in a regional system remain independent, and internal restructuring is usually not linked to the needs of the system, which makes the collaborative effort toward integration difficult at best. Further, administration of a regional system is shared among the participants under a separate management group umbrella.

There are many arrangements for this type of system, which may include a combination of independent hospital laboratories, consolidated laboratories, academic medical center laboratories, other independent laboratories, and commercial reference laboratories. Regional laboratories are uniquely positioned to serve their communities. The ability to keep the testing in the local community benefits the internal customers (laboratory employees), doctors (with shorter TAT), and patients (better continuity of care).

Outreach sales and marketing for the system are not a part of this model. Each laboratory would continue to market its services independently of the regional system, established primarily for managed-care opportunities (52). In a network model, independent laboratories affiliate under a network organization without any consolidation. In a consolidation model, two or more laboratories consolidate core operations to one primary site, operating rapid-access operations in remote sites. In a regional laboratory system, a hybrid operation is formed with participants from academic medical center laboratories, a commercial laboratory partner, and participating consolidated hospital laboratories.

In July 2013, Robert Michel reported a new trend and business model developing in academic medical centers (AMCs): the formation of integrated networks with various providers within a community and the surrounding region. This trend piggybacks on the healthcare reform movement to establish ACOs. Michel cites this as a response to recent payor actions to eliminate providers and narrow their networks, excluding high-cost providers like AMCs (53). The mutual objectives of the new model include:

- Each integrated network is anchored by an AMC and is designed to foster closer interaction between the academic subspecialists and the wider clinical community.
- For the pathology laboratories at the AMC, the associated integrated provider networks may often encourage participating physicians to send their reference and esoteric laboratory test referrals to the academic center and not to the physicians' primary laboratory service provider. (For more information, see reference 53.)

During the past decade, healthcare facilities have implemented various strategies to address the impact of the shrinking healthcare dollar on laboratory operations. The trend has shifted to more integrated delivery systems being created. In this model, hospitals eliminate redundancy by sharing services and moving the patient to a more cost-effective setting. Successful managers working in an integrated laboratory system will need additional knowledge and new skills, akin to industrial and systems engineering, combined with an ability to blend these skills with healthcare economics, fundamental business principles, human resource management, and information technology. Successful consolidated and regional networks will be the winners, leveraging their strengths, surpassing

the competition, and using exceptional customer services to create value, adding buying power in contract negotiations (54).

STRATEGIES FOR FUTURE SUCCESS

Strategic Redesign

Strategic redesign implementation takes a stepwise approach to implementation. First, an organization must decide to differentiate its products or services from the competition by adding value. Then, it must develop a structured process to add value and create an environment that welcomes change by empowering its employees. The organization needs a clear vision, a change leader to communicate the vision, and a management team that consistently "walks the talk" to accomplish the mission.

Next, the organization must review and redesign each necessary support process to eliminate steps that do not add value. According to Michael Hammer and James Champy in *Reengineering the Corporation: A Manifesto for Business Revolution* (70), process redesign involves the fundamental rethinking and radical redesign of business practices to achieve dramatic improvements in key performance measures such as quality, service, and timeliness. In strategic redesign, the quality indicators chosen for measurement should never be revenue-oriented but should include process cycle times, process costs, customer service costs, and patient outcomes. Leaders must celebrate improvement milestones with employees throughout the process and not just during implementation.

Supply Chain

There are enormous gaps between what we know and what we do. Typically, the time lapse from recognizing the need for process change to making the change happen is unacceptably long. Taiichi Ohno, a Japanese engineer at Toyota, developed the kanban system, which encompasses just-in-time inventory and assembly line production with no waiting to ensure continuity in the process flow. By studying Ohno's work, healthcare systems began to predict consumer demand accurately and allocate resources by anticipating the needs for care rather than reacting to them, virtually delivering healthcare kanban style (55). However, the COVID-19 pandemic exposed the vulnerability of a supply chain model that is built to reduce expenses and inefficiencies of warehousing, not one focused on ensuring continuous operation. In addition, COVID-19 demonstrated issues with the reliance on overseas vendors for many of the supplies used within the U.S. healthcare system and laboratories. Severe shortages of personal protective equipment, testing supplies, and other essential equipment exposed the inherent shortcomings of a supply chain system built upon the just-in-time model and foreign suppliers.

Due to the criticality of healthcare resources, healthcare organizations have begun to shift from just-in-time supply chain management, at least during the immediate aftermath of COVID-19, to a just-in-case model. The just-in-case model allows organizations to withstand supply chain shocks by increasing resiliency (56).

Laboratory Design

Most recently, a new design for laboratory space is emerging that creates environments that are responsive to present needs while also considering future demands. The designs include six key areas that require attention (57):

1. Create social space that fosters employee interaction and team-based performance.
2. Balance the amount of open and closed laboratory access.
3. Incorporate flexibility in design, including use of movable modular benches, to easily accommodate change.
4. Provide access for technology and electronic communications throughout the building.
5. Address environmental sustainability.
6. Develop and design locations that foster partnerships with internal and external customers.

Developing System-Wide Thinking and a Common Culture

Healthcare is suffering from internal turmoil and conflict resulting from the effects of restructuring, mergers, and acquisitions. To succeed in the future, hospital administration, employees, and physicians must develop an appreciation for each other's culture, values, beliefs, language, and goals. Once understood, a new system-wide culture can be agreed upon. The new system should incorporate business, clinical, and ethical dimensions by redefining the symbolic barriers of authority, tasks, and politics. If not identified early in the process, differences in ethical values will be the crux of ongoing conflict. To achieve the mutual goals, the following components are essential (58):

- Mutual understanding and agreement on system goals
- Enhanced communication between administration and physicians
- Greater physician involvement and oversight in the decision-making process
- Treatment based on evidence beyond controlling costs
- Emphasis on prevention, self-care, and outpatient services
- Focus on quality of patient outcomes working with multidisciplinary teams

Organizational climate and culture of trust. Developing a new culture is a difficult and time-consuming task. A common culture must be flexible and based on shared values and constant learning. A rigid culture is more focused on form. Trust is a perception and an attitude that influences how people accept change. Truthfulness, keeping promises, treating all employees fairly and equally, and respecting employees as individuals build trust within the organization (59).

Employees' perceptions about their working environment impact their ability to do a good job. Creating a desirable climate is essential for employee retention. Managers should provide a working environment that offers:

- *Flexibility*. With minimal red tape.
- *Rewards*. With performance feedback.
- *Responsibility*. Employees empowered to make independent judgments.
- *Clarity*. Goals and expectations must be clear.
- *Standards*. Hold each employee accountable to the same standards.
- *Team commitment*. Lead by example and create pride.

Organizations that create a culture with an atmosphere of trust among employees and customers maximize their intellectual assets and maintain a competitive advantage in the marketplace. Developing professional relationships and networks and strong lines of communication, promoting teamwork, and having a common mind-set are essential (60).

Differentiating a competitive advantage. As laboratories enter the 21st century and market pressures continue to increase, service industries, knowledge management, and virtual partnerships will lead to future survival. The strategies used to differentiate a competitive advantage will move away from a primary focus on cost containment to new strategies that include optimization of new and innovative products, flexibility of services, and formation of strong partnerships with stakeholders (suppliers, customers, employees).

The short-term survival mechanisms of cost-cutting, whether by restructuring, downsizing, or reengineering strategies, have not always resulted in increased productivity. Instead, these approaches will likely decrease morale, increase anxiety, and ultimately decrease productivity and innovation.

Loyalty-based management. The last and most critical step in achieving a competitive advantage is to create a business environment that sustains loyal customers. Developing a system-wide culture for understanding the economic effects of customer and employee retention on revenues and costs begins with management. Reinvesting cash flow from knowledgeable decisions attracts and retains loyal employees and loyal customers. When employees are satisfied and happy with their work, they are more productive, which ultimately leads to increased customer satisfaction. To properly evaluate the costs and benefits of a business decision, customer, product, and employee needs must all be synchronous. Loyalty-based management systems thrive on effective feedback measurements. Customers are an invaluable resource. Long-term employees are more familiar with the business and the needs of the customer. The ability to constantly deliver value in an ever-changing healthcare environment can only be accomplished through effective listening and learning. In the final analysis, loyalty-based management puts creating customer loyalty ahead of revenue. The only losers in this environment are the competitors who get the leftover customers and leftover employees (61).

Training Adequate, High-Quality Laboratory Professionals for the Future Workforce

The U.S. laboratory workforce issues encountered during and after the COVID-19 pandemic exacerbated the pre-pandemic staffing shortages. The large numbers of laboratory workers who retired or left the workforce altogether only accelerated the staffing shortages that had been predicted and discussed for decades. In 2021, there were approximately 45,000 laboratory testing personnel vacancies across the country, producing extreme demand for a minimal resource (62). One projection has estimated that the shortfall of laboratory testing personnel will be over 98,000 by 2025 (63). To further complicate the issue, the retirement rate among laboratory personnel is expected to exceed 20% in some laboratory areas over the next 5 years, leading to a significant loss of highly skilled technologists, especially more experienced supervisory staff (64). Because much of the laboratory staffing crisis was predicted and discussed long before it came to fruition, it is evident that many laboratories failed to address the issue proactively.

With approximately 4,900 Medical Laboratory Science (MLS) graduates and 2,900 Medical Laboratory Technicians (MLT) graduating each year in the U.S., any hope that academic institutions will provide the necessary personnel resource to fill laboratory vacancies is unlikely (65, 66). Therefore, alternative training programs must be created to meet the need for trained laboratory personnel. CLIA '88 outlines the training necessary to qualify to perform laboratory testing at various levels of complexity. More organizations must develop programs that train employees who meet CLIA and state licensure educational requirements to perform laboratory testing and become eligible for generalist or area-specific certifications.

Pathologist Shortage

In addition to the shortage of laboratory testing personnel, the shortage of pathologists across the U.S. is a significant concern. With the aging of the Baby Boomers and the expected correlated increase in laboratory workload, the shortage of pathologists must be addressed at a national level. As previously discussed, the implementation and use of telepathology can help, but it alone will not solve the shortage and workload issues.

Moving from Top-Down Management to Bottom-Up Customer Focus

Quality is one of the most talked about and least understood concepts in healthcare. It is a chameleon term that means different things to different stakeholders depending on their needs, beliefs, and motives. Informatics firms offer software tools that capture and measure quality without being able to demonstrate the impact and usefulness to their customers. Employers, insurers, and accreditation organizations demand provider commitment to quality improvement processes but have articulated only minimal standards for measuring and evaluating their effectiveness.

Collaboration is process-driven and results-oriented. Collaboration commits each side of the business relationship to fulfill their responsibilities and becomes the vehicle for implementing quality strategies. Each stakeholder's business needs must be met for quality management to become a core competency rather than a tactical business strategy. Business trust, cooperation, a realistic commitment to change, and collaboration are critical to achieving quality management (67). Everyone in healthcare involved in care delivery is a customer who depends on someone else for information or cooperation to get the job done. Recognizing interdependence and mutual reliance is fundamental in creating "networks of care" that can improve the quality of patient care while decreasing waste caused by care fragmentation (68). Placing the patient in the driver's seat ensures that we listen to and address patient needs. More reliable communication systems should decrease errors, prevent miscommunication, and avoid costly delays in the process, thereby streamlining the encounter.

Evidence-Based Medicine

Evidence-based medicine will encourage decision making based on reliable data. Science and technology have advanced rapidly over the last 4 decades, but the healthcare delivery system has fallen short in providing consistent, high-quality services to transfer its knowledge into practice. Evidence-based medicine allows the judicious integration of literature, clinical experience, and patient understanding. Based on scientific evidence, clinical guidelines and tools for measuring outcomes and patient compliance effectively bridge the gap between knowledge and practice.

In traditional medicine, the physician depends primarily on his memory, opinions formed without data, and anecdotal experience to prescribe treatment. The patient's participation is minimal. In evidence-based medicine, the physician incorporates current literature and data with memory and experience. The patient participates actively in making joint decisions about treatment modalities. The physician is monitored for adhering to guidelines, and the patient is monitored for compliance. Obtaining physician support in the quality-of-care movement is critical. Defining the appropriateness of care for patients, the appropriate practice for providers, and the appropriate payment from payors depends on evidence-based medical practices (69).

SUMMARY

The U.S. healthcare environment has not just changed but has begun to evolve. While this evolution is ongoing, the healthcare system as a whole has started the journey to expand health coverage, increase access, enhance health promotion, improve quality, and reduce costs. This evolution will continue to affect laboratories and how they are reimbursed and managed. Managing these continuous changes and their impact on laboratory delivery systems must be a significant focus of organizational leadership. Therefore, in the current changing healthcare environment, the modern laboratory can no longer afford to treat "change management" as a separate management subcategory. Rather, change management is now indistinguishable from routine laboratory management.

The changing healthcare environment has forced laboratory leaders to evolve as well. The changing U.S. healthcare environment now requires laboratory leaders to have a much broader skillset than ever before. A laboratory leader must be part scientist, healthcare administrator, clinician, medical coder, human resource generalist, marketer, and fortuneteller. As with other healthcare services, laboratory services are expanding beyond the traditional delivery modalities to increase patient access. While debates may arise over the risks and benefits of increased consumer-driven laboratory services, all indications are that these testing modalities are here to stay and will only continue to expand.

As the need for healthcare and laboratory services continues to grow, the shortage of pathologists and laboratory staff has already reached a critical level. The current and projected shortages seen across U.S. laboratories will require new and innovative ideas to resolve. As has been clearly demonstrated, the current education and staffing models are insufficient to meet staffing demands. In fact, they stopped working years ago, and it has just taken a while for those failures to significantly impact patient care.

As the U.S. healthcare delivery system evolves, laboratory operations and management will also continuously

need to advance. Laboratory leaders must fully understand how changes to healthcare delivery systems influence laboratory service delivery, reimbursement, and care coordination. Laboratory leaders who understand and can predict the impact of the changing healthcare environment will be better positioned to smoothly adjust course as needed and not simply arrive where they are currently headed.

KEY POINTS

- The healthcare environment continues to be a dynamic force.
- Healthcare reimbursement models are moving from a fee-for-service model to a value-based purchasing model.
- The PPACA contained several significant market reforms, consumer protections, and provisions to increase access to healthcare services.
- There have been a number of reimbursement reforms that integrate quality performance with a combination of reimbursement incentives or penalties.
- The core laboratory testing prototype is moving to a more real-time bedside model, even with few data supporting improvements in outcomes or decreased length of stay.
- Patient access to laboratory testing is continuing to expand beyond traditional disease monitoring to include at-home diagnostic testing as well.
- Mergers and acquisitions will continue to change the laboratory service model.
- The laboratory workforce issues will continue to mold the future of laboratory services and delivery.

GLOSSARY

Accountable care organization (ACO) A group of healthcare providers and suppliers of services, such as physicians and hospitals, that work together to coordinate and deliver seamless, high-quality, and cost-effective care for patients they treat under a fee-for-service or capitated payment arrangement.

Actuarial data Information used by an actuary to make projections regarding service utilization to determine the financial risk of providing the service.

Age/sex rating A method of structuring capitation payments based on enrollee membership age and sex.

Algorithm A binary decision tree using patient response to intervention and other information to guide stepwise treatment of a specific problem.

Bioinformatics The science of developing computer databases and algorithms for the purpose of speeding up and enhancing biological research and/or analysis of complex biological data.

Bundled payment CMS or a private payor links payments for multiple services that patients receive during an episode of care. For example, instead of a surgical procedure generating multiple claims from multiple providers, the entire team is compensated with a bundled payment that provides incentives to deliver healthcare services more efficiently while maintaining or improving quality of care. Providers will have flexibility to determine which episodes of care and which services would be bundled together.

Capitation A predetermined, fixed amount paid to providers in return for rendering a specified set of health services. The payment is usually on a per member per month (PMPM) basis related to the number of patients enrolled in the health plan.

Clinical pathway Practice guidelines for routine patient care that have been adapted to local conditions to standardize treatment. In more involved cases with underlying disease, treatment complications, and secondary unexpected issues with unknown outcomes, the practice guidelines are referred to as critical pathways.

Community-based rating A method of calculating insurance premiums based on the combined experience of multiple groups within a geographic region, adjusted for age, sex, and high risk.

Consolidation An internal laboratory system strategy to reduce costs by eliminating the duplication of services and excess capacity, restructuring of the workflow, implementing changes in staff resources, and centralizing operation management.

Consumer In healthcare, the consumer is the patient. The patient is sometimes also an employee, a subscriber, or a beneficiary.

Consumer-driven health plan (CDHP) A type of healthcare financing designed to reduce healthcare spending by providing financial incentives for consumers to receive/purchase the best value. Monthly premiums for CDHPs are typically less than the traditional health plan premium, giving consumers greater control and responsibility for their own healthcare spending. With higher deductibles and out-of-pocket costs, patients are incentivized to learn about the cost and quality of care.

Consumerism A healthcare market trend where patients decide what type of healthcare plan they need and how much to spend on it. Driven by decreases in employer-provided health insurance coverage and the development of financial vehicles such as tax-free savings accounts, employees are encouraged and incentivized to invest in their healthcare to ensure convenient access and improve quality.

Critical pathway Written criteria to guide care based on standards of practice, delineating necessary treatment and facilitating appropriate use of resources (also referred to as clinical pathway).

Diagnosis-related group (DRG) Classification system developed at Yale that defines 467 major diagnostic categories and places patients into case types based on the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10 CM) code classifications.

Direct access testing (DAT) Laboratory testing performed at the request of the patient as the consumer. These consumers want control of their medical care and are willing to pay for the service out of pocket.

Direct billing Medicare mandate that claims for laboratory services be submitted by the laboratory rendering the service and not billed by the provider that ordered the test.

Economy of scale Whenever output is increased without increasing the cost of production, economy of scale is achieved.

Electronic medical record (EMR) Documentation of the patient care treatment experience in an electronic format.

Episode of care The set of services required to manage a specific medical condition of a patient over a defined period of time.

Evidence-based measures Evidence-based practices integrate research evidence with the patient history and clinical impressions, using five steps—assess, ask, acquire, appraise, and apply—to evaluate the effectiveness of treatment and measure the outcomes.

Evidence-based medicine (EBM) The application of current best evidence from clinical research to the management of patient care, taking into account patient preferences and the physician's experienced judgment. The practice of evidence-based medicine allows for the judicious integration of literature, clinical experience, patient understanding, and needs.

Fee for service (FFS) The method of reimbursing providers a fee for each unit of service provided rather than by capitation, case rate, or per diem payment. Payment may be based on a percentage of charges or an agreed-upon fee schedule.

Fixed rate The negotiated payment rate for a service or group of services linked to a diagnosis code or procedure that is paid either prospectively or retrospectively.

Genomics The study of a person's genome and how genes interact with each other and the environment.

Health Reimbursement Arrangement (HRA) A plan that allows employers to provide nontaxable reimbursements to employees for qualified medical expenses. These expenses include monthly insurance premiums and out-of-pocket costs.

Kanban A Japanese system that monitors production line, inventory, consumer demand, and feedback to deliver goods and services just in time (JIT), an operational strategy used to eliminate waste by getting the right quantity of materials, supplies, and products in the right place at the right time.

Outcome A measured change or event that reflects the status of a patient during a defined period of time (for example, death, the onset of symptoms, the disappearance of symptoms, discharge, readmission, complications, or diagnosis).

Outcome-based medicine Medical practices aimed at assessing the quality and effectiveness of healthcare and measured against the ability to achieve a specified end result or outcome. Measures often include the following parameters: improved health, lowered morbidity or mortality, and improvement of abnormal states.

Payor Any third-party insurance company that sells traditional indemnity and managed-care products to group purchasers, large and small employers, and private individuals for healthcare coverage.

Per diem The negotiated daily reimbursement rate for services provided for inpatient hospital services. The rates are negotiated specific to the type of service rendered (for example, general medical, surgical, or intensive care).

Personalized medicine A healthcare patient model that customizes all healthcare decisions and clinical practices to the individual patient, incorporating the use of genetic and other information such as family history, social circumstance, environment, and behavior.

Point of service (POS) A managed care plan with reduced benefits that allows the enrollee to select services and benefits at the point of service for a network prepaid plan and an out-of-network fee-for-service plan. The out-of-network plan usually carries a copayment that is a percentage of the fee-for-service charges to the health plan.

Prospective payment system (PPS) A method for payment by Medicare for hospital inpatient services in which the payment is according to the DRG classification of the discharge and enacted by the Social Security Amendments of 1983 (P.L.98-21).

Proteomics The study of proteins on a large scale.

Purchaser Buying groups, employers, and individuals who purchase healthcare policies from third-party payors (insurers).

Referral A recommendation by the primary care physician that a member receive services from another network provider. It is a notification process and not a review to establish medical necessity.

Regionalization A system of laboratories capable of providing services to a larger geographical area. Regional systems allow the aligned laboratories to market the combined strengths of the collective testing menus to keep more tests within the regional system and eliminate referrals outside of the system, positioning the regional laboratory system to compete for managed-care contracts.

Restructuring Tactical measures used in laboratory consolidation include downsizing, point-of-care testing, consolidating work at benches, and interdisciplinary teams on utilization.

Tax, Equity, Fiscal Responsibility Act of 1982 (TEFRA) Public Law 97-248, which established payment for inpatient stays for Medicare beneficiaries based on diagnosis-related groups (DRGs) and introduced the clinical laboratory competitive bidding demonstration project.

Telecommunication Voice, video, or data information is transmitted from one location to another using integrated services digital network (ISDN) phone lines, T1 lines, digital subscriber lines, or various forms of wireless communication (43).

Telemedicine The practice of medicine using telecommunications technology to transmit data, sound, and images between two or more distant sites.

Telepathology A pathology practice using telecommunications technology to share diagnostic and microscopic images over long distances for identification and consultation, linking pathologists and other healthcare providers with patient care.

Value-based payment A payment method that rewards quality of care using payment incentives. Healthcare value is considered a function of quality, efficiency, safety, and cost, where providers are accountable for the quality and cost of the healthcare services they provide. The payments are based on rewards that are dependent on meeting specific performance measures and on consequences that discourage patient care that is inappropriate, unnecessary, and costly.

REFERENCES

1. **Congress.gov.** 1989. H.R.3299 – Omnibus Budget Reconciliation Act of 1989. 101st Congress (1989–1990). https://www.congress.gov/bill/101st-congress/house-bill/3299. Accessed 22 May 2022.

2. **Wouters A**, **Bennett S**, **Leighton C**. 1998. Alternative provider payment methods: incentives for improving health care delivery. *Prim Policymakers Ser* **1**:12.

3. **Barnum H**, **Kutzin J**, **Saxenian H**. 1995. Incentives and provider payment methods. *Int J Health Plann Manage* **10**:23–45.

4. **Casto AB**, **Layman E**. 2006. *Principles of Healthcare Reimbursement*. American Health Information Management Association, Chicago, IL.

5. **Congress.gov.** 1973. H.R.7974 – Health Maintenance Organization Act of 1973. 93rd Congress (1973–1974). https://www.congress.gov/bill/93rd-congress/house-bill/7974. Accessed 24 May 2022.

6. **Verrilli DK**, **Zuckerman S**. 1996. Preferred provider organizations and physician fees. *Health Care Financ Rev* **17**:161–170.

7. **KFF**, **Claxton G**, **Rae M**, **Young G**, **Mcdermott D**, **Whitmore H**, **Kerns J**, **Cifuentes J**, **Damico A**, **Strange L.** 2020. *Employer Health Benefits 2020 Annual Survey*. Kaiser Family Foundation, San Francisco, CA. https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf. Accessed 19 September 2023.

8. **Takemura Y**, **Beck JR**. 2001. Laboratory testing under managed care dominance in the USA. *J Clin Pathol* **54**:89–95.

9. **HealthCare.gov.** Affordable Care Act (ACA). Glossary, HealthCare.gov. https://www.healthcare.gov/glossary/affordable-care-act/. Accessed 10 May 2022.

10. **HHS.gov.** New HHS data show more Americans than ever have health coverage through the Affordable Care Act. https://www.hhs.gov/about/news/2021/06/05/new-hhs-data-show-more-americans-than-ever-have-health-coverage-through-affordable-care-act.html. Accessed 10 May 2022.

11. **Guth M**, **Garfield R**, **Rudowitz R**. 2020. The effects of Medicaid expansion under the ACA: updated findings from a literature review. *Kaiser Fam Found.* **37**:944–950.

12. **Centers for Medicare & Medicaid Services (CMS).** 2019. HHS Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017. 83 FR 67816. https://www.federalregister.gov/documents/2018/12/31/2018-27981/medicare-program-medicare-shared-savings-program-accountable-care-organizations-pathways-to-success. Accessed 9 September 2023.

13. **Quality Payment Program.** 2022. Qualified clinical data registry (QCDR) measure specifications. https://qpp.cms.gov/resources/document/d33c1886-141f-4185-bd5e-17049b2ee653. Accessed 22 May 2022.

14. **National Association of ACOs.** https://naacos.memberclicks.net/. Accessed 10 September 2023.

15. **Quality Payment Program**. 2023. Reporting options overview. https://qpp.cms.gov/mips/reporting-options-overview. Accessed 11 May 2022.

16. **Slen J**, **Bailit M**, **Houy M**. 2010. Value-based purchasing and consumer engagement strategies in state employee health plans: a purchasing guide. Academy Health and State Coverage Initiatives, Robert Wood Johnson Foundation. http://www.statecoverage.org/files/SCI_Value_Based_Report%20-%20Final.pdf.

17. **Blumenthal D**, **Abrams M**. 2020. The Affordable Care Act at 10 years—payment and delivery system reforms. *N Engl J Med* **382**:1057–1063.

18. **Congress.gov.** 2014. H.R.4302 – Protecting Access to Medicare Act of 2014. 113th Congress (2013–2014). https://www.congress.gov/bill/113th-congress/house-bill/4302.

19. **College of American Pathologists.** 2023. Protecting Access to Medicare Act (PAMA) for laboratories. https://www.cap.org/advocacy/laboratory-oversight-and-regulation/protecting-access-to-medicare-act-for-laboratories. Accessed 11 May 2022.

20. **Xu J**. 2015. Laboratory data in ACO environments. https://clpmag.com/disease-states/cancer/laboratory-data-aco-environments/. Accessed 11 May 2022.

21. **Miles J**, **Weiss RL**. 2011. The role of laboratory medicine in accountable care organizations. ARUP Laboratories. https://www.aruplab.com/files/resources/suite/ACO%20Lab%20Strategy_whitepaper.pdf.

22. **Page L**, **Fields R**. 2015. 13 legal issues for hospitals and health systems. Becker's Hospital Review. https://www.beckershospitalreview.com/hospital-management-administration/13-legal-issues-for-hospitals-and-health-systems.html. Accessed 28 April 2022.

23. **The HIPAA Journal.** 2023. Healthcare data breach statistics. https://www.hipaajournal.com/healthcare-data-breach-statistics/. Accessed 21 May 2022.

24. **Nichols JH**. 2021. Utilizing point-of-care testing to optimize patient care. *EJIFCC* **32**:140–144.

25. **Gorman E.** 2000. The new futures of diagnostic testing. *Clin Lab Manage Rev* **14**:26–29.

26. **Tate JR**, **Johnson R**, **Barth J**, **Panteghini M**. 2014. Harmonization of laboratory testing - Current achievements and future strategies. *Clin Chim Acta* **432**:4–7.

27. **Brailer D.** 2001. Peer-to-peer technology: connection tops collection. *Health Manag Technol* **22**:28–29.

28. **Marques MB**, **McDonald JM**. 2000. Defining/measuring the value of clinical information. *Clin Leadersh Manag Rev* **14**:275–279.

29. **Bissell M.** 1996. Defining laboratory related outcomes measures: establishing a link to patient focused care. *Clin Lab Manage Rev* **10**:95–97.

30. **McQueen MJ**. 2001. Overview of evidence-based medicine: challenges for evidence-based laboratory medicine. *Clin Chem* **47**:1536–1546.

31. **Skjei E.** 2002. Getting ready for the bioinformatics shakeup. *CAP Today* **16**:1–6.

32. Hausfater P, Hajage D, Bulsei J, Canavaggio P, Lafourcade A, Paquet AL, Arock M, Durand-Zaleski I, Riou B, Oueidat N. 2020. Impact of point-of-care testing on length of stay of patients in the emergency department: a cluster-randomized controlled study. *Acad Emerg Med* **27**(10):974–983.

33. Singer AJ, Taylor M, LeBlanc D, Meyers K, Perez K, Thode HC Jr, Pines JM. 2018. Early point-of-care testing at triage reduces care time in stable adult emergency department patients. *J Emerg Med* **55**:172–178.

34. Lovic R, Gentry J. 1984. *Dimensions in Healthcare*. Peat, Marwick, Mitchell & Co, Philadelphia, PA.

35. Noah B, Keller MS, Mosadeghi S, Stein L, Johl S, Delshad S, Tashjian VC, Lew D, Kwan JT, Jusufagic A, Spiegel BM. 2018. Impact of remote patient monitoring on clinical outcomes: an updated meta-analysis of randomized controlled trials. *NPJ Digit Med* **1**:1–12.

36. Goldman DP, Chen C, Zissimopoulos J, Rowe JW, Research Network on an Aging Society. 2018. Opinion: Measuring how countries adapt to societal aging. *Proc Natl Acad Sci USA* **115**:435–437.

37. Keehan SP, Cuckler GA, Poisal JA, Sisko AM, Smith SD, Madison AJ, Rennie KE, Fiore JA, Hardesty JC. 2020. National health expenditure projections, 2019–28: Expected rebound in prices drives rising spending growth. *Health Aff (Millwood)* **39**:704–714.

38. Lehmann C. 2002. Management of point-of-care testing in home health care. *Clin Leadersh Manag Rev* **16**:27–31.

39. Scott K. 2023. Legal and regulatory hurdles in digital pathology and telepathology. https://www.clinicallab.com/trends/clinical-lab-compliance/legal-and-regulatory-hurdles-in-digital-pathology-and-telepathology-21817. Accessed 14 June 2023.

40. Lasiter L, Samboy J, Leibowitz C, Mathews C, Hoskyns S, Abels E. 2023. Aligning reimbursement for digital pathology with its value. *Precision Med Q*. https://www.thejournalofprecisionmedicine.com/the-journal-of-precision-medicine/aligning-reimbursement-for-digital-pathology-with-its-value/. Accessed 3 April 2022.

41. Rainer R. 2000. Is telepathology right for your lab? *Adv Adm Lab* **9**:53–57.

42. Holton J. 2002. Meeting the needs of the pay-at-the-pump generation. *Health Manag Technol* **23**:78–79, 77.

43. Rader B, Gertz A, Iuliano AD, Gilmer M, Wronski L, Astley CM, Sewalk K, Varrelman TJ, Cohen J, Parikh R, Reese HE, Reed C, Brownstein JS. 2022. Use of at-home COVID-19 tests—United States, August 23, 2021–March 12, 2022. *MMWR Morb Mortal Wkly Rep* **71**:489–494.

44. Ayala-Lopez N, Nichols JH. 2020. Benefits and risks of direct-to-consumer testing. *Arch Pathol Lab Med* **144**:1193–1198.

45. Barletta G, Zaninotto M, Faggian D, Plebani M. 2013. Shop for quality or quantity? Volumes and costs in clinical laboratories. *Clin Chem Lab Med* **51**:295–301.

46. Kaufman, Hall & Associates, LLC. 2021. M&A quarterly activity report: Q2 2021. https://www.kaufmanhall.com/sites/default/files/2021-07/kh-ma-2021-q2-activity-report_final.pdf. Accessed 24 May 2022.

47. Song Z, Ferris TG. 2018. Baby boomers and beds: a demographic challenge for the ages. *J Gen Intern Med* **33**:367–369.

48. United States Census Bureau. 2021. Historical population change data (1910–2020). https://www.census.gov/data/tables/time-series/dec/popchange-data-text.html. Accessed 23 May 2022.

49. Hirschman S. 1994. Merger mania strikes MCOs, but is bigger better, or will it be harmful to market competition? *Manag Healthc* **1994**:5.

50. Definitive Healthcare. 2023. How many IDNs are in the U.S.? https://www.definitivehc.com/resources/healthcare-insights/idns-us. Accessed 9 September 2023.

51. South SF. 1999. Seeking the competitive advantage: it's more than cost reduction. *Clin Lab Manage Rev* **13**:173–178.

52. Michel R. 1997. Regional lab systems beginning to emerge. *Dark Rep.* **4**:5–14.

53. Kirk P. 2013. Vanderbilt University Medical Center forms nation's largest clinically integrated network that includes its own health insurance offering. *Dark Daily*. http://www.darkdaily.com/vanderbilt-university-medical-center-forms-nations-largest-clinically-integrated-network-that-includes-its-own-health-insurance-offering#axzz2Z7ptXIJS. Accessed 23 May 2022.

54. Salk J, Ray F. 1997. The buoyancy of laboratory networks. *Adv Adm Lab* **6**:76–80.

55. Berwick D. 2000. Knowledge always on call: for docs, practicing medicine will mean providing information more than providing care. *Clin Leadersh Manag Rev* **14**:250–252.

56. Jiang B, Rigobon D, Rigobon R. 2021. From just-in-time, to just-in-case, to just-in-*worst*-case: simple models of a global supply chain under uncertain aggregate shocks. *IMF Econ Rev* **70**:141–184.

57. Watch D. 2016. Trends in lab design. *Whole Building Design Guide*, a Program of the National Institute of Building Science. https://www.wbdg.org/resources/trends-lab-design. Accessed 23 May 2022.

58. Swisher KN, Begun JW, Ulmer DL. 1999. Hospital-physician relationships in the integrated delivery system: an ethical analysis. *Clin Lab Manage Rev* **13**:3–12.

59. Neuhauser PC, Bender R. 1998. Merging, partnering, and restructuring: coping with the culture clashes. *Clin Lab Manage Rev* **12**:405–409.

60. Harari O. 1999. The trust factor. *Clin Lab Manage Rev* **13**:28–31.

61. Reichheld FF. 1993. Loyalty-based management. *Harv Bus Rev* **71**:64–73.

62. Oster NV, Guenther G, Frogner BK, Skillman SM. 2021. The clinical laboratory workforce in the U.S: supply, distribution, educational pathways, and state responses to the COVID-19 emergency. https://nmu.edu/clinicalsciences/sites/clinicalsciences/files/2021-07/Clinical_Policy-Brief-June-14-2021.pdf. Accessed 23 May 2022.

63. Kavilanz P. 2018. The US can't keep up with demand for health aides, nurses and doctors. https://money.cnn.com/2018/05/04/news/economy/health-care-workers-shortage/index.html. Accessed 23 May 2022.

64. Garcia E, Kundu I, Kelly M, Soles R. 2022. The American Society for Clinical Pathology 2020 vacancy survey of medical laboratories in the United States. *Am J Clin Pathol* **157**:874–889.

65. ASCLS. 2020. Addressing the clinical laboratory workforce shortage. https://ascls.org/addressing-the-clinical-laboratory-workforce-shortage/. Accessed 23 May 2022.

66. Schwartz L, Cymrot C. 2020. Factors influencing MLS career choice amid the COVID-19 pandemic: a cross-sectional study. https://assets.researchsquare.com/files/rs-71466/v1/9951fc1c-2f50-417a-a117-35c724de2680.pdf?c=1631854999. Accessed 23 May 2022.

67. Boland P. 1993. Quality prerequisites for providers, purchasers, and payors. *Manag Care Q* **1**:1–3.

68. Carmone AE, Kalaris K, Leydon N, Sirivansanti N, Smith JM, Storey A, Malata A. 2020. Developing a common understanding of networks of care through a scoping study. *Health Syst Reform* **6**(2):e1810921.

69. Ellrodt G, Keckley P. 2001. Evidence based medicine, where medicine and technology meet. *Health Manag Technol* **22**:44–46.

70. Hammer M, Champy J. 1993. *Reengineering the Corporation: A Manifesto for Business Revolution*. Harper Business, New York, NY.

II

Managerial Leadership

(SECTION EDITOR: **Deirdre L. Church**)

5 **The Foundations of Leadership**
David S. Hefner and Katharine R. Becker

6 **Employee Needs**
Kathleen G. Beavis

7 **Motivating through Intelligent Leadership**
Christa Pardue

8 **Effective Communication**
Marianna Hofmeister

9 **Effective Meetings**
Mark G. Hanly

10 **Conflict Management**
Christopher Naugler

11 **Leading People Through Change in Pathology and Laboratory Medicine**
Gabriel E. Ayala

5

The Foundations of Leadership

David S. Hefner and Katharine R. Becker

Introduction

Distinguishing Management from Leadership
What Is "Leadership" and How Do You Become a Leader? • Management • Leadership

The First Foundational Factor Is Integrity
The Definition of Integrity • Honoring Your Word • The Pitfalls in Honoring Your Word • What Is Your Word? • What Is the Current State of Your Word? • Trust and Its Relationship to Honoring Your Word • Preparation for Making a Commitment or Giving Your Word

The Second Foundational Factor Is Authenticity
The Definition of Authentic • Knowing Yourself • How Do You Respond in Various Situations? • The Importance of Context • The Path to Authenticity

The Third Foundational Factor Is Commitment to Something Bigger than Yourself
Succeeding as a Leader • What Happens Next?

SUMMARY

KEY POINTS

ACKNOWLEDGMENTS

REFERENCES

APPENDIXES

OBJECTIVES

To help the reader understand the difference between the realms of management and leadership

To develop an understanding of the importance of integrity and its relationship to performance

To clarify the misconceptions about operating with integrity and why people may disregard it, thereby diminishing their power as a leader

To help aspiring leaders appreciate the inward journey of leadership and discover for themselves what it means to be authentic

To provide clarity about the relationship between being committed to something bigger than oneself and becoming a leader

To offer resources for the reader's continued education

Whatever you can do or dream you can, begin it.
Boldness has great genius, power and magic in it!

Johann Wolfgang von Goethe

Being a leader has everything to do with Goethe's quote. Every leader has faced the challenge to "just begin it!" This chapter offers access to actionable pathways for developing the foundational elements that are key to leading and exercising leadership effectively. You do not need to master these foundations first, but they will be important for ensuring effectiveness in your leadership journey. Being a leader is a lifetime endeavor; once you step out, everything is different and there is no turning back. Healthcare today needs leaders at every level and in each discipline to succeed in solving complex problems with intra-disciplinary solutions that can deliver cost-effective, high-quality care and ensure the health of all.

Distinguishing Management from Leadership

What Is "Leadership" and How Do You Become a Leader?

How do you answer these questions about leadership? A 2021 Google search for "leadership" returned more than 2.8 billion entries, which is not at all helpful, as you may only want the five best explanations. If you seek expert guidance to find a useful definition as a starting point, you will discover that the faculty teaching leadership courses know that there are as many definitions of

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch5.

leadership as books written about it. In 2021, Amazon listed more than 60,000 book entries. Add to this the overwhelming amount of contradictory information that conventional wisdom offers, such as "a really good clinician will be a great leader," or "leadership is the same as good management," or "leadership is only for people with a position near the top," or "people must be born with the inherent ability to become leaders."

The critical first step in answering the questions about leadership posed above is to understand what management is and how it differs from leadership. Management and leadership operate in different realms (Table 5.1). Managers are accountable for a known scope and use a set of well-developed skills to manage in their area. Conversely, leaders are responsible for and function in an unknown scope, using quite different skills to exercise leadership effectively.

Management

The *Oxford English Dictionary* explains the term *manager* as derived from an Italian verb, *maneggiare*, which means "to handle, train, and be in charge of, control horses." Today, managers are assigned accountability to oversee the processes dealing with or controlling things or people. Managers' roles and accountabilities include coordination of, and interaction with, employees; gathering, analyzing, and sharing data or information; problem solving and decision making; producing results; operating within a budget; and accounting for the status of everyone and everything within their scope of accountability. Larger organizations often have up to three levels of manager phenotype—top, middle, and supervisory—and at each level, the scope of accountability varies, and in some cases overlaps.

High-performing staff members are often promoted to be managers. Some succeed and others learn that managing is not to their liking. The shift to a manager's role challenges strong performers to delegate and develop others. The role requires moving from self-managing to mobilizing employees to tackle tough problems. A manager's success is frequently measured by the results of those they manage. Managers need to be taught skills to succeed in their new role. These skills cover a range from effective delegation, to developing credible and reliable budgets, to delivering performance evaluations, to having difficult conversations, and to fostering a diverse, equitable, just, team-based workforce. A manager's role requires many diverse activities and meetings, such as providing incentives and recognition for work well done or implementing layoffs when the circumstances require it. A manager's authority is limited and tends to remain within their assigned area or scope, and their actions must align with senior management decisions and the organization's articulated strategies. Tasks are frequently identified and assigned by middle- or top-level managers with the authority to make such delegations. After 40 years of teaching

Table 5.1 Management and leadership: important characteristics and functions[a]

Management	Leadership
Overseeing processes dealing with or controlling things or people (known scope) that include: • Coordination and interaction with employees • Handling, sharing, and analyzing information • Problem solving and decision making • Operating within a budget	Working within the unknown (something bigger than your current base of knowledge) • Making something happen in the future that would not have otherwise happened • Navigating in uncertainty and ambiguity • Self-generating comfort to experiment (trial and error) • Having enthusiasm that inspires the engagement of others
Typical organizational management levels: • Top • Middle • Supervisory	Available to anyone at any position in an organization who embraces important foundational elements: • Operating with integrity • Being authentic • Being committed to a bold future
Shift from focus on performing well to mobilizing employees, with success measured by the results of those managed • Results set by top-level managers and strategy	Understanding the differences between keeping your word and honoring your word • Trust is the outcome of honoring one's word, and successful leaders engender the trust of those being led and/or managed • Your word is what you said you will do or will not do • Once agreed upon, you honor your word • Communicating clearly what was or was not done is honoring your word
Management authority • Limited • Bounded within their assigned area	Authenticity is the degree to which one is true to one's self • Without authenticity, one will not succeed as a leader • A leader acknowledges his or her successes as well as failures

[a] While not mutually exclusive, leadership skills can be found among managers. The focal differences seem to be the willingness to work in the "unknown" versus the "known" arena and being committed to something bigger than yourself.

and working with managers, the authors have found that managers are often interested in being taught how to "manage up," or to get *their* manager(s) to do what *they* think should be done. If the concept of managing up is of interest, one needs to understand that it has more to do with being a leader than managing.

Leadership

In contrast to the work of managing a known scope, a leader's work is *to make something happen in the future that was otherwise not (predictably) going to happen*. Leaders must have the courage to take on being responsible for what is unknown, the sense-making ability to navigate in uncertainty and ambiguity, the comfort to experiment using trial-and-error methods to discover the way, and the enthusiasm to inspire the engagement of others to achieve progress when the pathways are uncertain or current knowledge argues that the vision being articulated cannot or will not happen (1).

How does one become a leader? As your parents may have told you, anyone (you) can exercise effective leadership in any arena of concern, or from any position in an organization. However, to succeed in being a leader and to exercise leadership effectively require the development of a foundation upon which your confidence to lead grows and is recognized by others.

Can leadership be taught? Does understanding what other leaders have done or knowing the styles they used help someone to lead? The editors of a recent book, *The Handbook for Teaching Leadership*, reported an interesting conclusion after interacting with 30 leadership academics during the publication of this book about their varied teaching methods (2). In more than 25 years of using many methods of teaching about leadership and leadership styles and studying cases to learn what leaders do, the authors found "scant empirical evidence that any of these approaches work" (2). In addition, there is insufficient research and an inconsistent body of knowledge to validate whether the methods being used succeed in developing the kind of leaders needed for the uncertain future we face (3). While teaching skills and imparting knowledge are what educators know best to do, "the current state of leadership education lacks the intellectual rigor and institutional structure to advance beyond its present (and precariously) nascent stage" (2). In fact, only one of 30 different teaching methods in *The Handbook for Teaching Leadership* has the objective of leaving students actually being leaders and exercising leadership effectively (4, 5). Many of the perspectives in this book chapter are derived from, or are a synopsis of, the ground-breaking material developed to support the precept of actually being an effective leader (4, 6–9).

So, you may rightly ask, can this chapter possibly be different? While we cannot reach through these pages and shape you into a leader, the material in this chapter offers access to foundational elements that provide potency and bring power to leading. While they can also improve your management, embracing them is critical for anyone desiring to be a leader and to exercise leadership effectively. The choice to build your foundations, or not, will be up to you.

> *Few will have the greatness to bend history itself. But each of us can work to change a small portion of events, and in the total of all these acts will be written the history of this generation.*
>
> Robert F. Kennedy

The First Foundational Factor Is Integrity

> *The softest pillow is a clear conscience.*
>
> Narayana Murthy, founder and former CEO, Infosys

When you ask people what *integrity* is, their answers are often expressed as values or norms or in the context of morality. For instance, someone with integrity does not lie or steal. While there are moral, legal, and ethical underpinnings in every situation, organization, or professional group, integrity (as described here as a foundation for leadership) is not a normative or relative phenomenon (4, 6–8). Integrity is independent. Yet it underlies everything, and without integrity, nothing works. Without being a person of integrity, you can set aside the notion of leading effectively, and to be a person of integrity will be a never-ending undertaking.

The Definition of Integrity

To understand this area, we start with the 2021 *Merriam-Webster Dictionary* definition of "integrity":

1. the quality of being honest and having strong moral principles; moral uprightness
2. the state of being whole and undivided

Rarely do people notice the second component of the definition. However, it is critical to providing an actionable access to operating with integrity. If you focus on the second definition, the notion that integrity establishes the underpinning for workability and performance becomes clear. We ask you to consider the following heuristic: as integrity (undivided, whole) increases, the conditions that allow for maximum performance also increase. Therefore, integrity is a critical condition of performance.

But what does it mean for a person or a leader to be undivided and whole? For a person to operate with integrity means to have their word and their actions be undivided and whole or, said another way, to *honor one's word*. To clarify what honoring one's word means, we examine what is meant by one's word in the next sections.

Honoring Your Word

Honoring your word simply means doing what you said you would do, or if you cannot or will not be doing what you said, letting others know as soon as you know (in advance of the promised deadline) that you will not be doing what you said, and that you are willing to deal with the resultant consequences. Though this concept sounds relatively simple, many people do not understand (or they disregard) how important and necessary honoring one's word is to optimal performance, both individually and collectively throughout their organization. We are sure you can think of instances in which people say they will do something, do not do it, and never mention it again. Common misconceptions become pitfalls that often prevent people from honoring their word (6, 10).

The Pitfalls in Honoring Your Word

Many people fail to let others know what they did or did not do. When a deliverable is due they remain silent, especially when it is not done, even after the fact when others know it was not done. Have you ever awakened in the middle of the night in a panic as a due date or a deadline approaches, because you didn't know if your team member(s) delivered what was necessary for your success or not?

The first pitfall in the arena of honoring one's word occurs when people think that integrity is only a virtue. If integrity is assumed to be a virtue, rather than a necessity, it conceals the fact that honoring your word is a necessary condition for performance. As a virtue, integrity can become more easily sacrificed, especially when it appears to a person that he or she must do so to prosper, or that it does not matter because no one else really cares. For instance, reporting only the good news, or the news you think others want to hear, can seem to be acceptable or clever behavior; or saying you finished something that you in fact did not, because it sounds better and you know you will get to it soon. What is unseen or not easily recognized in these situations is the resulting impact and damage to individual and/or organizational performance.

When integrity is understood as *honoring your word*, then saying both what is and is not happening—the good, the bad, and the ugly—becomes dependable behavior. In environments where reliable information is readily available, managers can make more appropriate decisions and effectively address what is (or is not) getting done. For instance, if a manager knows what was not done, and the stakeholders who are expecting the deliverable are alerted to the potential delay, they can discuss together if the deliverable can be delayed until a later date or if it must be completed now or some alternative could suffice. As more people learn to speak openly about what is and is not done, individual and organizational confidence to do this grows, and productivity will increase. Honoring your word helps to establish workable relationships and to develop a sufficient sense of security that people will more naturally provide complete, accurate, and timely information.

A second pitfall occurs when managers are *unaware* that they themselves have not honored their word or have missed a deadline. For years, we authors have discussed with managers and staff at all organizational levels the importance of honoring their word. Many have admitted that they take better care of their cars than they do their word, because they can "see" their car but they cannot "see" their word. Managers have so much to do; it seems almost impossible to know what all the outstanding commitments are that must be completed (especially when many commitments are delegated via email, often without discussion). Even when managers *do* know what has not been done, their energy may be focused on explaining *why* they did not complete the commitment or on being asked to construct a report justifying their nondelivery, rather than communicating what was not done and focusing instead on the impact and possible solutions. When managers and staff operate without full awareness of their commitments, they are clearly unaware of the increased potential for a decline in performance, not only in their area of accountability, but in their organization's performance and/or their own personal performance. It does not take staff long to determine if deadlines are reliable or not, or if their managers know the outcomes they are working on (or not). Reliable performance declines in settings where managers don't know. If you see the level of performance decreasing in your area of accountability *and* it seems like everyone is honoring their word, to get back on track you should consider, "When was performance last progressing at necessary or acceptable levels and/or when did it go off track—and at that point in time, what happened and what commitments were not fulfilled or honored?"

The third pitfall in honoring your word occurs when people think integrity means *keeping* your word or that you must always do what you said. As presented in this chapter, *keeping one's word* and *honoring one's word* are not synonymous. However, most people think the two are one and the same.

What happens when it is impossible (or when it is inappropriate, perhaps due to legal reasons, strategic reasons, force majeure, etc.) to fulfill what was previously committed? In such situations, working to *keep* your word, when it is not possible to produce the intended outcome(s), can waste precious time. It is more appropriate to immediately *honor* your word by letting others know what you will not or did not do, then refocus your performance appropriately (6, 9). When being open and transparent is not embraced in an organization, it leads to counterproductive behaviors such as not answering email in a timely manner or avoiding people and meetings, impairing the coordination of performance. When a leader cannot keep his or her

word and opts for the apparent short-term move of concealing it, rather than openly acknowledging it, he or she may forfeit the power and respect that will accrue from honoring one's word. And without the respect of others, you can forget about being a leader.

Once you understand what it means to honor your word, and how to honor your word, it becomes important to understand what is included in your word.

What Is Your Word?

To be a person of integrity requires that you understand how your word is constituted and that you own the implications of your word from the following five different perspectives (6, 9).

First, your word is what you *said* you will do or will not do, and in the case of saying you *will* do something, doing all of what was specified and doing it on time. When someone asks you to do something, what they have asked you to do becomes your word unless you respond to the person in a timely fashion saying that you will not be doing it.

Second, your word includes what you *know* to do or not to do, unless you have said something explicitly to the contrary to the relevant parties. When you know what there is to do (or not do), it becomes your word.

Third, your word includes doing what is *expected* of you to do or not do (and in the case of do, to the specifications and on time), unless you have explicitly said to the contrary to the relevant parties. Please take note of an apparent paradox: while your word includes all that is expected of you, what you expect from others is not for themselves their word unless they have said they will do it (6).

Fourth, what is expected of you includes all of the *moral, ethical, and legal standards* for your role or profession that you have not explicitly declined. These standards, whether spoken or not, are part of your word.

Fifth, your word includes *what you say is possible* or *what you stand for*, as a declaration made to one or more people or even to yourself, and it includes taking the actions necessary to realize what you stand for or declare (6, 9).

What Is the Current State of Your Word?

Take a moment to reflect on the current state of your word, where is it honored and communicated or where there might be work to do to restore any damage done by not honoring it. After reflecting for yourself, consider your staff, your department, and areas of accountability. Have there been missed deliverables, or is there an interface your staff has with another part of the organization where performance is lower than it could or should be that has been tolerated or unmentioned? In your areas of accountability, do you have the necessary tracking, reporting, and measuring in place to effectively manage the myriad commitments you and your teams are accountable for? Reports and metrics should help you and your department/organization to succeed, not be a waste of time to prepare; change them if they are wasting time. What you can see, you can move and manage. What you cannot see, you cannot manage with integrity. Be sure you and your staff have sufficient tracking tools to record and manage all commitments you are accountable for in a timely manner.

Lastly, investing the time it may require to restore honoring your word where commitments are incomplete or unaligned with expectations, or are inconsistent with your leadership objectives, will result in a noticeable increase in overall performance. Don't forget to acknowledge people for being reliable!

Trust and Its Relationship to Honoring Your Word

The literature on trust talks about "walking the talk," and says that to be trusted, you must keep your word. Everyone learns at an early age the consequences of not doing what they said they would do. In some cases, such people are called liars, but no matter what people are called, it is a very uncomfortable position in which to be. Many people have told us they have learned that the way to avoid getting caught in this bind is never to make promises and to avoid commitments altogether. However, as explained above, keeping your word is not the same as honoring your word, and you may not always be able to keep your word. In fact, unless you give your word to virtually nothing of significance, or make only certain-to-happen commitments, both of which are counter to being a leader, you will not always be able to do what you said. When it is impossible or inappropriate to keep your word, either producing the outcome or delivering by the deadline, or when you choose not to, or you find you cannot keep your word, honoring your word allows you to operate with integrity.

It is often surprising to people that research shows that you will engender a greater degree of trust and admiration, even when you do not keep your word, if you honor your word by saying that you did not or will not be able to do what you said. In Service Encounter Satisfaction research, 23% of the reported "most memorable satisfactory" encounters involved situations where there had been a failure in a core service delivery, and it had been acknowledged openly (11). This finding is striking, as it suggests that service delivery system *failures* can be remembered as highly satisfactory encounters. One generally assumes that failures can be mitigated by employees who are trained to respond, but the fact that such incidents were remembered as very satisfactory is somewhat surprising (11). Results like this can occur when an organization or person responds in a forthright manner, saying what did or did not happen, and offers to clean up the resulting "mess" or explains what will be done to ensure that it does not

happen again, rather than hiding, denying, or covering up what actually happened.

Successful leaders engender trust, but trust is not something one can build or work on directly. It is the result of your being recognized by others, through your actions, as a person who honors his or her word. Trust is not the same as likeability—you certainly have the experience of people whom you like but do not trust. To be trusted by others is incredibly important for leaders. The path to being someone who is trusted is operating with integrity, and the path to operating with integrity is honoring your word (6).

Preparation for Making a Commitment or Giving Your Word

With so much at stake in the area of integrity, trust, and performance, it is important to consider fully, *before* you give your word, what it will take to keep it. Multiple discussions and analyses of the benefits and costs over a period of time may be needed for stakeholders to fully determine whether to give their word or make a commitment. When being asked for a "yes" or "no" response, if uncertain, a good leader does not give a flippant answer; rather, they ask for some appropriate amount of time to do an analysis with their team, after which such a response will be provided. Seeking the counsel of those who will be working on the commitment, getting their ideas and input for determining possible pathways and strategies to accomplish the outcome(s), builds a respect and alignment that is a hallmark of great leaders. The time to do these types of analyses is *before* giving your word, not afterwards. How many times have you wondered why the boss didn't ask you before making a commitment you would have to deliver! After your word is given, you need to honor your word, not deal with whether you should have given it or not.

The most common source of failed leadership today comes from being irresponsible or casual about one's word and, by extension, the word of the organization. Operating without integrity is a major source of operational mistakes and significant declines in performance, and it often leaves a professional stain in people's careers or lives. In some cases, it has destroyed large, seemingly indestructible corporations. People who lack the strength to operate with integrity are dangerous when faced with difficult counterforces that challenge their judgment. To be a leader, you must know yourself as a person of integrity, have the courage to maintain this core value in the gray areas, consistently honor your word to others, and be known to do the appropriate thing, time after time.

There is more discussion about this topic in the next section on authenticity, and for more on the subject of integrity and its importance in leadership, see references 6 and 9 and Appendix 5.1.

The Second Foundational Factor Is Authenticity

> *The price they have to pay for leadership is unceasing self-discipline, constant taking of risks, and the perpetual inner struggle.*
>
> Charles de Gaulle

Authenticity has historical underpinnings in philosophy, art, and psychology, and has become important to both managing and leading today. In philosophy, the conscious self is seen as coming to terms with being in a material world and encountering external forces, pressures, and influences that are very different from itself. Authenticity is reflected by the degree to which one is true to one's own values, spirit, or character, despite these external forces. Without authenticity you will not succeed as a leader.

The Definition of Authentic

The 2021 *Merriam-Webster Dictionary* definition of "authentic" is as follows.

1. a. worthy of acceptance or belief as conforming to or based on fact
   b. conforming to an original
   c. made or done the same way as an original
2. not false or imitation: REAL, ACTUAL
3. true to one's own personality, spirit, or character
4. a. *of a church mode*: ranging upward from the keynote
   b. *of a cadence*: progressing from the dominant chord to the tonic
5. *obsolete*: AUTHORITATIVE

Will the *real you* please stand up (12, 13)? Sounds bizarre, right? However, many people spend their lives being the way they think others want or expect them to be, rather than what is true for them or what they know best to do. What about you? Is your freedom to express yourself diminished in a meeting with people you do not know, or those with higher positions in the organizational hierarchy than yours? Authenticity is gauged by expression. It reflects both the extent to which you know and show your true self and the extent to which you deploy yourself in ways that are appropriate to the situations you are facing (14).

Knowing Yourself

Let us start with who the real you is. As attributed to Socrates in some of the earliest accounts about authenticity, "The unexamined life is not worth living" (15). Becoming a leader requires you to take an inward journey, or quest of introspection and reflection, in order to develop a profound sense of yourself, your spirit, what made you that way, and what your values are (15). For guidance on this journey, we recommend the exercises and questions

designed to assist you in reflecting and discovering important personal insights that are available in *Finding Your True North*, by Bill George, a former CEO of Medtronic who taught a semester-long course on authentic leadership at the Harvard Business School (16). This journey is not about changing who you are; rather, it is about revealing the limiting ways *you wound up being*, which include your knee-jerk behaviors and outdated opinions of whatever may have happened in the past (17). The process frequently involves reframing or rewriting your stories about your experiences to date, and when done well, it will leave you with grounding and freedom to tackle tougher challenges involving greater risk and ambiguity. Leaders rarely fail from lack of intelligence. Rather, research has shown that hundreds have failed due to lack of emotional intelligence, which is composed of self-awareness, motivation, empathy, social skill, and self-regulation (10). When people are left with the sense that there is a fundamental congruency between who you are, your life story, the values you espouse, and your actions, and that you have made a transformation from self-concern to concern for empowering and inspiring others, they are likely to see and experience you as authentic and someone whose leadership they could follow.

How Do You Respond in Various Situations?

The next step is considering how you deploy yourself, and whether you act appropriately to the situations you are facing. Understanding how you got to be the way you are supports this aspect of authenticity by enabling you to recognize past situations in which you have responded with an inappropriate action and the fallout that resulted. Once you fully understand your responsibility for such events and their consequences, you can take steps to repair any resultant disorder and restore the affected relationship(s). In this process you may discover other, more effective or appropriate behaviors with which you can respond differently to similar situations in the future.

Consider this bold assertion: in every leadership situation, your actions and behaviors will always be correlated with the way in which the situation occurs for you (4, 7). From a neuroscientific perspective, "occurs" corresponds to that which is generated by neural networks in the brain that produce your experiential perceptions, via senses, that we project onto the external world (17). For instance, if a situation occurs for you as exciting, you cannot wait to begin; if the same situation seems frightening, you dread having to participate and may delay beginning. In either case, your behaviors and actions will be synchronized with your interpretation of the situation or, in this vernacular, how the situation occurs or appears for you (4, 7). In being a leader when something occurs to you as hopeless, your ways of being and acting will convey hopelessness to others, and no matter how encouraging your words are, others will perceive the inauthenticity and will be hesitant to engage or, worse, will be unsuccessful in addressing the situation.

The Importance of Context

What people fail to recognize is that the context they bring to any situation is decisive and has a direct relationship with how the situation will occur for them (7, 8). Taking the effective actions in leading is correlated to the way in which the situation you are facing occurs for you and how it occurs for you is colored or shaped by the context you bring (4, 5). Self-reflection helps to reveal your unexamined contexts, many of which originated in childhood and leave you with blind spots, unable to see things others can see. Brain research has determined that we "see" with our brains not with our eyes.

> If visual sensations were primarily visually received rather than constructed by the brain, you'd expect that most of the fibers going to the brain's primary visual cortex would come from the retina. Instead, scientists have found that only twenty per cent do; eighty per cent come downward from regions of the brain governing functions like memory. Richard Gregory, a prominent British neuropsychologist, estimates that visual perception is more than ninety per cent memory and less than ten per cent sensory nerve signals (reference 18, p. 9).

Once unexamined contexts, adopted in childhood or adolescence, are discovered, they can be shifted to be appropriate for the situations you are facing today as a fully competent adult. Having a strong sense of yourself, how you got to be the way you are, and your values provides an anchor when you find yourself in a swirl of conflicting pressures, and leaves you with the courage to follow through—even when you are directly threatened or challenged—in a way that is consistent with your values and those of the organization.

You need to answer the question "Why would anyone be led by me?" This is a strange question, and it can only be answered by making reference to personal qualities that are authentically yours, and not as attributes of the position you hold. Effective leaders have reached an equanimity and inner peace with themselves, both their strengths and weaknesses, so they are not compelled to hide their weaknesses or else be caught in the fatal error of thinking they must always appear to be perfect or successful.

The Path to Authenticity

The path to developing authenticity is increasing your ability to be courageous and transparent about your failures, your weaknesses, and where you are being

inauthentic (everyone is inauthentic from time to time or in certain situations) (4, 8). Being open is not meant to imply that you divulge everything to everyone or in every situation, rather that you come to terms with your shortcomings by fully owning who you are and how you grew to be the person you are today, coupled with understanding that you can move beyond your historical ways of being, with a freedom and ease that come from sharing about your own developmental path with others.

Personal insecurity is a petri dish for breeding inauthentic behavior. When you pretend to be what you are not, people recognize it immediately. Asking others for input and subsequently disregarding their input because you had already made a decision conveys pretentiousness. If you are not open to input, do not ask for it; faking it will cost you authenticity.

The more you grasp that you are not able to see objective reality as it is—the role of context in coloring everything—and that being a leader is not about you being perfect or knowing everything, the more you will seek and rely on input or support from others. See if you can reflect on the freedom provided in accepting that there is an objective reality which is independent of us and that our access to that reality is through perceptions generated in our brains. Most people argue that their view is real and right, never accepting that they could be missing something. When you are free to not know and to discover again, you will find that the challenges in healthcare today do not *occur* the same for all the stakeholders, and this awareness increases the need to form diverse teams to understand and tackle them. This insight can expand one's appreciation and tolerance for variety of thought, and open one to input from multiple and even conflicting sources as an indispensable means of operating and leading others. Knowing yourself, knowing your strengths and weaknesses, and being open about them empower the people you lead and manage to make more relevant contributions, engage more authentically, and derive more satisfaction from their job.

The ultimate context for exercising effective leadership is to stand for being responsible for your experience of life, for whatever is now and will be in the future. Responsibility begins with the willingness to acknowledge that you are the source of your universe of experience and the events in your life. Ultimately, it is a context from which one chooses to live. Responsibility is not burden, fault, praise, blame, credit, shame, or guilt. In responsibility there is no evaluation of good or bad, right or wrong (19). True responsibility cannot be assigned from outside one's self by another; it is a stand or declaration that one can create to empower oneself and one's experience of being cause in the matter. As a leader, the context of responsibility expresses itself by having the openness for others to be responsible and experience themselves as cause in the matter, and to respect and support them as such.

What de Gaulle said is true of anyone who aspires to be a leader. Why would anyone subject themselves to that? Both the answer, and what actually distinguishes leading from managing, are found in the third foundational factor, discussed next. Leaders are responsible for, and function in, an unknown scope. Their job as a leader begins the moment they commit to something that they, and perhaps others, have never done before. They must have the courage to commit to be responsible for what is unknown. Where does that courage to make such commitments come from? Why would someone make such a commitment?

The Third Foundational Factor Is Commitment to Something Bigger than Yourself

> *Seek, above all, for a game worth playing. Such is the advice of the oracle to modern man. Having found the game, play it with intensity—play as if your life and sanity depended on it. (They do depend on it.) . . . Move as if your movements had some purpose. If life does not offer a game worth playing, then invent one. For it must be clear, even to the most clouded intelligence, that any game is better than no game at all.*
>
> Robert S. de Ropp (18, 20)

Succeeding as a Leader

Your success in being a leader has a lot to do with discovering or inventing what matters enough to you to be unreasonable with yourself and others about making something happen in the future that was otherwise, not predictably, going to happen. Some call this "purpose" and say that, without purpose, leaders are at the mercy of their desires for power, prestige, or financial rewards (16). Purpose, or being someone who is up to something bigger than yourself, drives you as a leader, becomes the source of your power, and gives you the courage and confidence to keep going and the strength to take risks. It also helps when the time comes to explain to others what it is that inspires you, where your passion and energy come from, and it may, in some cases, motivate, inspire, and empower them.

How can you discover your purpose? If you are going to be authentic, you cannot adopt someone else's purpose; you must find your own. What is it that you want to make happen that is unlikely to happen otherwise?

Answering this question requires reflection and, in most cases, conversing with others. You can begin by considering what really matters to you, or thinking about times when you read the news and something resonated with you or made you think this should or should not be

happening, or why can't we do that, or why are we tolerating this or that? You might ask others who know you well what they see you are most interested in or animated about, to help you land in an area that is important for you. Whatever you find, start to think: if my wildest dreams were realized, what might be the new reality? Take time to define a bold, declarative statement of the possibility to which you are willing to dedicate your life's energy and intellect to realize, something that otherwise would not predictably happen, something you and others around you do not know how to do. Without such a commitment you will not be a leader.

In a certain sense, all leaders are heroes, ordinary people whose being and acting are bigger than their historical selves because they derive a sense of self from what they are committed to. Whatever the commitment is, it is beyond their personal concerns, and in most cases has little or no direct personal payoff. As these commitments are acted on, such big, impossible promises create something to which others can be committed, which leaves them with a sense that their lives are also about something bigger than themselves. This is the entrée into being a leader and exercising leadership effectively.

Not everyone will choose such a path and become a leader. To do so is a personal choice, a step that must be authentically taken. Once you step out, there is no turning back, and stepping out is not always easy, especially when which action to take is clouded by many unknown elements, risks, and ambiguities. Arrows can fly. Second-guessing can abound. Hearing from those who have gone before you as a leader may shed some light on what can result from being committed to something bigger than oneself:

> It is not the critic who counts, nor the man who points out how the strong man stumbled, or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena; whose face is marred by dust and sweat and blood; who strives valiantly; who errs and comes short again and again; who knows the great enthusiasms, the great devotions, and spends himself in a worthy cause. Who, at the best, knows in the end the triumph of high achievement; and who, at the worst, at least fails while daring greatly . . .
>
> President Theodore Roosevelt, speech at the Sorbonne, 1910

What Happens Next?

Once you have invented a possibility that is bigger than yourself and committed to make that possibility a reality, you will need new skills, many of which are discussed in detail in the following chapters. One of the most important skills involves listening effectively. As Steven Covey said, "Seek first to understand, then to be understood" (reference 21, p. 235). By enhancing your listening skills, you will begin to hear not only what is being said, but more importantly, what is not being clearly said or stated at all. You may notice that you are able to hear when people are making commitments that you cannot count on. When you hear inauthentic responses or promises, stop the action. Take time and discuss the deliverables and deadlines and give others a second chance to consider whether or not they can successfully deliver. Do not let weak commitments slide by; too much is at stake.

Another important leadership skill is to find ways of speaking about the future that make it seem real and palpable to others, so they can become as inspired about that future as you are and join you in taking the requisite actions to make that future happen. You will discover that you need to stay open to input, whether it is supportive or challenging, as you never know where the next piece of critical data you will need might come from. Make sure to have intermediate and long-term measures to guide your actions, pay attention to these measures and results, listen keenly to all feedback, and evaluate and make any necessary midcourse corrections to continue taking ground and making progress. Communicate, communicate, and then communicate some more. Celebrate the victories, help people make sense of the dead ends, and stay open to learning along the way, because you are on a journey no one else has taken. In the times of inevitable despair, when your thoughts are filled with doubt or self-concern, find someone you trust—maybe an advisor, mentor, or coach—with whom you can freely discuss what you are thinking. Then recreate the future possibility you committed yourself to, and renew your resolve to realize it.

As every superhero you ever watched knew, in their quest to make their world a better place, things will not always work the way you think they should. When superheroes find themselves in disarray on the ground, they know . . .

> *There is only enough time to iron your cape . . . and back to the skies for you!*
>
> Attributed to Jason Harley, DARPA Transportation Team member (see Appendix 5.2)

SUMMARY

To be a leader requires that you establish a strong foundation on which you can build a context for exercising leadership effectively in any leadership situation. In this chapter, we present you with an understanding of how to establish this foundation for yourself. We would like to leave you speculating about what you would undertake if you knew you could not fail. When you find your answers, the foundational elements will be there when you step out

into the realm of leading. In the following chapters of this book, you will see how the use of different leadership skills can influence people and alter their performance.

KEY POINTS

The following are 30 often forgotten and important tips for good leadership. We thank Major General Perry M. Smith, USAF (Ret.), for renewing his permission to include these as key points of this chapter. These are from part 1 of 60 tips that were first published in the *Marine Corps Gazette* (22). They reinforce the material presented.

- *Know yourself*. All leaders should realize they are, in fact, four or more people. They are who they are, and who they think they are (and these are never the same); they are who their bosses think they are; and who their subordinates think they are. Leaders who work hard to get feedback from many sources are more likely to understand and control their various selves, and hence be better leaders.
- *Develop mental toughness*. Leaders must be brutally honest with themselves or they will slip into the terrible habit of self-deception. Even the best leaders make mistakes. By smoking out these mistakes and correcting them quickly, a good leader can become a superb one.
- *Be magnanimous*. Leaders who share their power and their time can accomplish extraordinary things. The best leaders understand that leadership is the liberation of talent; hence they gain power not only by constantly giving it away, but also by not grabbing it back.
- *Squint with your ears*. The most important skill for leaders is listening. Introverts have a great edge, since they tend to listen quietly and usually don't suffer from being an "interruptaholic." Leaders should "squint with their ears." Too many bosses are thinking about what they will say next, rather than hearing what is being said now. They are guilty of "fake listening."
- *Trust your instinct and your impulse*. If something smells bad, sounds funny, or causes you to lose sleep at night, take another look. Your instincts combined with your experience can prevent you and your organization from walking off a cliff.
- *Learn by failure*. In my professional career, I have learned much more from my failures than from my successes. As a result, I have become tolerant of the honest failure of others. When a major setback comes along, try to treat it as a marvelous learning experience, for most certainly it will be just that. To quote General George Patton, "Success is how high you bounce after you have hit bottom."
- *Protect innovators*. A Medal of Honor recipient from Vietnam, Army Col. Jack Jacobs, worked for me for three years. He is by far the most innovative person I have ever known. Well over 50% of his ideas were awful, but buried among these bad ideas was an occasional pearl of great wisdom. I learned that I had to protect Jack and my organization from his bad ideas while encouraging him to present all his ideas, so we could use his great ones.
- *Beware of certainty*. Leaders should be a bit skeptical of anyone who is totally certain about his or her position. All leaders should have a decent doubt, especially when dealing with "true believers" who are always sure they are right.
- *Be decisive*. Top leaders usually must make prudent decisions when they only have about 60% of the information they need. Leaders who demand nearly all the information are usually months or years late making decisions.
- *Don't become indispensable*. Organizations need indispensable institutions, not indispensable people. Leaders should not allow themselves to become indispensable, nor should they let any of their subordinates do so.
- *Avoid the cowardice of silence*. During meetings, so-called leaders often sit on their hands when it is time to raise a hand and speak up. Leadership requires courage—courage to make waves, courage to take on our bosses when they are wrong, and the courage of conviction. Every Robert E. Lee needs a James Longstreet to tell him exactly the way it is.
- *Fight against paranoia*. Welcome criticism; help people understand that it is OK to have "love quarrels" with the organization. Loyalty and criticism are mutually supporting while slavish loyalty is deadly. Avoid the defensive crouch. Never attribute to malice that which is adequately explained by stupidity.
- *Be goal oriented*. Leaders, even at a lower level, must try to set some long-term goals for their associates and for their organization. People want to know where they are going and in what order of priority.
- *Follow the platinum rule*. The golden rule is marvelous. But in leadership situations, the platinum rule may be even better: "Treat others the way they would like to be treated."
- *Don't waste people's time*. The best question a leader can ask a subordinate during a counseling session is "How am I wasting your time?" Not everyone will tell you, but cherish the ones that do, for they will help you grow and prosper as a leader.
- *Thank the invisible people*. There are lots of fine people doing great work who seldom get thanks because they are "invisible." They work so quietly and so competently that they often are not noticed

by the leader. Handwritten thank-you notes are especially appreciated.

- *Don't send out "I don't trust you" messages*. People who say "I never want to be surprised" or "Check with me before you start anything" or "I'm off on a trip; I will call in every morning for an update" are sending out very strong "I don't trust you" messages to their subordinates. People who know they are not trusted will never contribute at their full potential.
- *Serve, don't humor the boss*. Too many leaders see their big tasks as keeping their bosses happy, getting to the bottom of the in-box, or staying out of trouble. That is not what leadership is all about. Leadership is serving the mission, serving your people, and being frank in your dealings with your boss.
- *Criticize up, praise down*. Leaders must deflect at least some of the bad guidance they get from above. Your subordinates expect you to criticize the boss on occasion. Don't disappoint them.
- *Be physically fit*. Everyone has a "health age." If you exercise regularly and watch your diet, you can make yourself four or five years younger than your chronological age. If you are too busy to exercise, you will, over time, damage yourself and those you serve.
- *Develop solid leadership skills*. The best leaders are superb at listening and time management and are competent in speed reading, dictation, and the use of manual and electronic brainstorming techniques.
- *Help your people understand you*. When you take over a new organization, get your key people together and tell them what your top priorities and your pet peeves are. It is especially important for them to learn very early what really bugs you. They will appreciate your candor.
- *Smoke out those of low integrity*. Leaders must sniff the air constantly to ensure high standards of ethics are maintained. In almost all large organizations, someone is walking out the back door with something. Expense accounts, personnel records, training reports, and contracts need regular scrutiny.
- *Concentrate on performance, not just results*. How you get results is important. Leaders who don't concern themselves about the process and the performance that lead to the results are making a big mistake. Always ask yourself what it took to gain those great results.
- *Maintain a sense of outrage*. There are many super-cool managers who worry too much about keeping their bosses happy and staying out of trouble. As a result, they never allow themselves to be outraged when the system is doing serious damage to those who work for them. The best leaders get mad occasionally, and using controlled outrage can often make right wrongs that are levied upon their people.
- *Beware of intimidation*. Be very careful here. Some bosses allow themselves to be intimidated by outsiders, by their bosses, and even by their subordinates. An intimidated boss can never be a great leader. You have to have an independent mind to make the right choices.
- *Avoid the activity trap*. Don't confuse being busy with being productive. Without discipline, managers can become slaves to their meetings, travel schedules, in-boxes, computers, and telephones. Don't get so wrapped up in the minutiae that you become paper pushers and "in-box managers" rather than visionary leaders.
- *Build a robust brain trust*. One of the great secrets of leadership success is to have a brain trust of experts on various issues. A brain trust of around 300 really smart, well-connected, and quick-thinking friends can be very helpful whenever you need help. Be sure to have their office and home phone numbers and their email addresses handy, so you can get hold of them quickly. The brain trust is reciprocal: they help you and you help them. Within your large brain trust have a smaller "ethics brain trust." When you face a tough ethical issue, this group can be very helpful. My ethics brain trust really helped me as I made the decision to resign from CNN in June 1998.
- *Beware of the Paul principle*. Too many leaders allow themselves to slowly slide downhill in competence. When they lose touch with the issues, the new technologies, and the people, they have fallen victim to the "Paul principle." Many who were highly effective leaders during their first few years have lost it by year 10.
- *Get ready for the future*. The future is coming fast. Leaders need to think about the future and prepare their people for it. To keep a close eye on the future, join the World Future Society and read two magazines regularly—*Business Week* and *The Futurist*. All leaders must work hard to build the future, for that is where they and their associates will spend the rest of their lives.

ACKNOWLEDGMENTS

The authors thank Werner Erhard, Michael Jensen, Kari Granger, Wiley "Chip" Souba, and Major General Perry M. Smith, USAF (Ret.), for their dedication to leadership development and their contribution to our thinking. And we thank our spouses for their encouragement and never-ending support.

REFERENCES

1. **Ancona D.** 2012. Sensemaking: framing and acting in the unknown, p 3–19. *In* Snook S, Nohria N, Khurana R (ed), *The Handbook for Teaching Leadership: Knowing, Doing, and Being*. Sage Publishing, Los Angeles, CA.

2. **Snook S**, **Nohria N**, **Khurana R (ed).** 2012. *The Handbook for Teaching Leadership: Knowing, Doing, and Being*. Sage Publishing, Los Angeles, CA.

3. **Snook S**, **Nohria N**, **Khurana R**. 2012. Introduction: teaching leadership—advancing the field, p xii–xiii. *In* Snook S, Nohria N, Khurana R (ed), *The Handbook for Teaching Leadership: Knowing, Doing, and Being*. Sage Publishing, Los Angeles, CA.

4. **Erhard W**, **Jensen MC**, **Zaffron S**, **Granger KL**. 2011. Course materials for: "Being a Leader and the Effective Exercise of Leadership: An Ontological/Phenomenological Model." Harvard Business School NOM Working Paper No. 09-038; Simon School Working Paper No. 08-03; Barbados Group Working Paper No. 08-02. Social Science Electronic Publishing, Rochester, NY. http://ssrn.com/abstract=1263835. Accessed 1 September 2021.

5. **Erhard WH**, **Jensen MC**, **Granger KL**. 2012. Creating leaders: an ontological/phenomenological model, p 246–261. *In* Snook S, Nohria N, Khurana R (ed), *The Handbook for Teaching Leadership: Knowing, Doing, and Being*. Sage Publishing, Los Angeles, CA.

6. **Erhard W**, **Jensen MC**, **Zaffron S**. 2009. Integrity: A Positive Model that Incorporates the Normative Phenomena of Morality, Ethics and Legality. Harvard Business School NOM Working Paper No. 06-11; Barbados Group Working Paper No. 06-03; Simon School Working Paper No. FR 08-05. Social Science Electronic Publishing, Rochester, NY. http://ssrn.com/abstract=920625. Accessed 1 September 2021.

7. **Erhard W**, **Jensen MC**, **Barbados Group**. 2010. A New Paradigm of Individual, Group, and Organizational Performance. Harvard Business School NOM Unit Working Paper No. 11-006; Barbados Group Working Paper No. 09-02. Social Science Electronic Publishing, Rochester, NY. http://ssrn.com/abstract=1437027. Accessed 1 September 2021.

8. **Erhard W**, **Jensen MC, Zaffron S, Echverria J**. 2023. Course materials for: "Being a Leader and the Effective Exercise of Leadership: An Ontological/Phenomenological Model" [Revised 2023]. Harvard Business School NOM Working Paper No. 09-038; Simon School Working Paper No. 08-03; Barbados Group Working Paper No. 08-02. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1263835#. Accessed 20 July 2023.

9. **Jensen MC**, **Granger KL**, **Erhard W**. 2010. A New Model of Integrity: The Missing Factor of Production. Harvard Business School NOM Working Paper No. 10-087; Barbados Group Working Paper No. 10-03. Social Science Electronic Publishing, Rochester, NY. http://ssrn.com/abstract=1559827. Accessed 1 September 2021.

10. **Goleman D.** 1998. What makes a leader? *Harv Bus Rev* **76**:93–102.

11. **Bitner MJ**, **Booms BH**, **Tetreault MS**. 1990. The service encounter: diagnosing favorable and unfavorable incidents. *J Mark* **54**:71–84.

12. **Souba WW**. 2006. The inward journey of leadership. *J Surg Res* **131**:159–167.

13. **Souba W.** 2011. Perspective: a new model of leadership performance in health care. *Acad Med* **86**:1241–1252.

14. **Goffee R**, **Jones G**. 2011. Teaching executives to be themselves—more—with skill: a sociological perspective on a personal question, p 151–161. *In* Snook S, Nohria N, Khurana R (ed), *The Handbook for Teaching Leadership: Knowing, Doing, and Being*. Sage Publishing, Los Angeles, CA.

15. **Baggini J.** 2005. Wisdom's folly. *The Guardian*. www.guardian.co.uk/theguardian/2005/may/12/features11.g24. Accessed 1 September 2021.

16. **George B.** 2012. Authentic leadership development, p 313–328. *In* Snook S, Nohria N, Khurana R (ed), *The Handbook for Teaching Leadership: Knowing, Doing, and Being*. Sage Publishing, Los Angeles, CA.

17. **Pfeffer J**, **Fong CT**. 2002. The end of business schools? Less success than meets the eye. *Acad Manag Learn Educ* **1**:78–95.

18. **Gawande A.** 2008. The itch: its mysterious power may be a clue to a new theory about brains and bodies. *The New Yorker*. www.newyorker.com/reporting/2008/06/30/080630fa_fact_gawande. Accessed 25 January 2013.

19. **Erhard W**. 2010. Responsibility. Werner Erhard Quotes. https://wernererhardquotes.wordpress.com/2010/01/22/responsibility-begins-with-the-willingness-to-take-the-stand-that-one-is-cause-in-the-matter-of-one%E2%80%99s-life-it-is-a-declaration-not-an-assertion-that-is-it-is-a-context-from-which-one-choos/. Accessed 20 July 2023.

20. **De Ropp RS**. 2002. *The Master Game: Pathways to Higher Consciousness*. Gateway Books and Tapes, Nevada City, CA.

21. **Covey SR**. 1990. *The Seven Habits of Highly Effective People*. Simon and Schuster, New York, NY.

22. **Smith P.** 1997. Learning to lead. *Mar Corps Gaz* (January):36–40.

APPENDIX 5.1 Resources

Erhard W, **Jensen MC**, **Zaffron S**. 2009. Integrity: A Positive Model that Incorporates the Normative Phenomena of Morality, Ethics and Legality. Harvard Business School NOM Working Paper No. 06-11; Barbados Group Working Paper No. 06-03; Simon School Working Paper No. FR 08-05. Social Science Electronic Publishing, Rochester, NY. http://ssrn.com/abstract=920625. Accessed 1 September 2021.

George B, **Sims P**. 2007. *True North: Discover Your Authentic Leadership*. Jossey-Bass, San Francisco, CA.

Jensen MC, **Granger KL**, **Erhard W**. 2010. A New Model of Integrity: The Missing Factor of Production. Harvard Business School NOM Working Paper No. 10-087; Barbados Group Working Paper No. 10-03. Social Science Electronic Publishing, Rochester, NY. http://ssrn.com/abstract=1559827. Accessed 1 September 2021.

Snook S, **Nohria N**, **Khurana R (ed).** 2012. *The Handbook for Teaching Leadership: Knowing, Doing, and Being*. Sage Publishing, Los Angeles, CA.

Souba W. 2011. Perspective: a new model of leadership performance in health care. *Acad Med* **86**:1241–1252.

APPENDIX 5.2 Further Information

Dugan R. 2012. From Mach-20 glider to humming bird drone. TED video. Posted by TEDtalksDirector, March 27, 2012. www.youtube.com/watch?feature=player_embedded&v=V_LurJfOSiA#t=0s. Accessed 1 September 2021.

6

Introduction
Definitions and Background
Special Challenges from the Pandemic
Strategies for Assessing and Reducing Burnout
Additional Trends and Needs of Laboratory Employees
The Role of Generational Differences
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENTS
REFERENCES

Employee Needs

Kathleen G. Beavis

OBJECTIVES

To understand burnout and its impact on laboratory workers

To learn strategies to detect and reduce burnout

To be aware of special needs of new employees and generational differences

It is dangerous to make everybody go forward by the same road: and worse to measure others by oneself.

Saint Ignatius of Loyola

the covid-19 pandemic has brought to the forefront employee needs which have been simmering quietly. Burnout has been recognized as a risk to medical professionals for over 50 years, but most studies have focused on physicians and nurses (1, 2); until recently there was little research on burnout in the clinical laboratories. The American Society for Clinical Pathology (ASCP) surveyed job satisfaction, burnout, and well-being in 2018 and presented the findings as they related to pathologists (1), trainees (3), and laboratory professionals (technologists, technicians, managers, and supervisors) (1). While one-third of pathologists and trainees felt burnout at the time of the study, the rates were even higher among laboratory professionals (1). Over 85% of laboratory professionals had felt burnout at some point, and half (49.9%) were experiencing it at the time of the survey (1). This is particularly noteworthy because the survey was conducted before the pandemic put additional stresses on all laboratory professionals, especially those working in microbiology laboratories.

Definitions and Background

Burnout has been variously defined as "exhaustion, cynicism, and reduced effectiveness" (4) and "emotional exhaustion, depersonalization, and loss of sense of personal accomplishment" (2). For the purposes of the ASCP study, burnout was described as "feeling overwhelmed, feeling emotionally exhausted, not caring about work, and feeling a low sense of value or accomplishment" (1).

Even though a small study documented burnout in 48% of medical technologists 40 years ago (5), burnout has not received much attention until recently. Changes in the healthcare industry as well as in health reform legislation have increased pressures on laboratory professionals. These changes include consolidation of laboratories and price competition, as well as a move

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch6.

to patient-centered care and patients' feedback about their healthcare experience. The consolidation and price competition demand employees who are efficient; patient satisfaction demands employees who are effective and engaged. An "engaged" employee is the opposite of a burned-out employee; engagement can be characterized by "vigor, dedication, and absorption in work" (4).

Burnout affects the individual as well as patients and the institution. Risks to the individual include depression as well as maladaptive behaviors such as alcohol and drug abuse. Risks to the patient include decreased productivity as well as increased errors. Risks to the institution include increased sick days, job-seeking behavior, and decreased patient satisfaction (2, 6).

Special Challenges from the Pandemic

Superimposed on the now smoldering issue of burnout have been the more recent impacts of the SARS-CoV-2 (COVID-19) pandemic. These have affected all laboratory workers, with additional impacts on the youngest professionals. A workforce study conducted by the ASCP and University of Washington estimated that 24% of respondents indicated that their laboratory implemented furloughs lasting longer than 1 month (7). Many laboratory workers endured both financial challenges, as family members were laid off, as well as additional responsibilities in caring for sick relatives or managing the education of children. Many laboratory workers worried about bringing the virus home after pipetting and testing specimens from those infected with COVID-19. All laboratory professionals were impacted by a mandated loss of the camaraderie that can strengthen the work community. The imposition of masks (and often face shields) for over 2 years made communication more challenging for all employees, especially for those hired during the pandemic or who did not have established friendships or sources of support in the workplace. Restrictions on groups of employees eating and relaxing together, both at work and outside of work, further retarded development of informal friendship and mentoring relationships as well as more formal educational and mentoring opportunities, all of which are so crucial to the success of new laboratory hires.

The youngest people joining the work force, also known as Gen Z, were sometimes furloughed or fired from their first job (8). Those who were away at school were told, often with very little notice, to vacate their dormitories and classrooms in the spring of 2020. These students lost connections to friends, professors, coaches, and other mentors. Internships and learning experiences in hospital laboratories were delayed, rushed, or transitioned to online. As structured learning in hospital laboratories decreased, opportunities to transmit the lessons of the hidden curriculum of professionalism, and how one conducts oneself in a workplace, also vanished.

The pandemic has interrupted the development of some aspects of emotional intelligence for Gen Z. Emotional intelligence—"self-awareness, self-regulation, motivation, empathy, and social skills"—can be taught and learned (8). As "life" shut down, many young people had to adapt to new ways of learning, and many had to pivot and take on additional responsibilities in the family, losing the opportunity to explore personal and career motivations and to discover fulfilling activities. Gen Z will bring strengths such as empathy and adaptability into the workplace. They are also likely to be more cognizant of the emotions of their coworkers, having endured so much personal disruption as well as the losses and sadness of friends and family (8).

Strategies for Assessing and Reducing Burnout

As the challenges of burnout have been compounded by the challenges of the pandemic, burnout in healthcare workers has become a high priority for organizations. Reasons for this attention include the increasing prevalence of burnout among healthcare professionals, as well as the recognition that affected professionals are less productive, commit more errors, and are more likely to change jobs and/or careers (2). There has also been a recognition that the organization and work environment play a major role in burnout, and so combating burnout and restoring engagement are a shared responsibility among organizations, work units, and employees. The Mayo Clinic has identified seven "dimensions" whose interplay can lead to the exhaustion, cynicism, and inefficacy of burnout, or to the vigor, dedication, and absorption of engagement: (i) workload, (ii) efficiency, (iii) flexibility/control over work, (iv) work-life integration, (v) alignment of individual and organizational values, (vi) social support/community at work, and (vii) the degree of meaning derived from work (4).

There are individual, organizational, and work unit factors which influence each of these dimensions (Table 6.1), as well as organizational strategies that can promote wellness. Acknowledging and assessing burnout in the organization's laboratory staff is an important first step. Several modalities can be used to acknowledge the problem, including town halls and face-to-face meetings with work units and hospital or laboratory leadership. Just as organizations measure patient satisfaction and financial performance, the well-being of employees can also be measured with standardized assessment tools. Both the Maslach Burnout Inventory and the Oldenburg Burnout Inventory (9, 10) can be used for several categories of healthcare professionals. Other standardized assessments

Table 6.1 Drivers of burnout and engagement, with examples of individual, work unit, and organization factors that influence each driver, with a focus on laboratory professionals[a]

Drivers of burnout and engagement	Individual factors	Work unit factors	Organization factors
Workload and job demands	Laboratory specialty Work location Decision to work overtime to increase income	Productivity expectations Team structure Efficiency Available tools and supplies	Staffing Method of compensation (seniority or productivity) Payor mix
Efficiency and resources	Experience Ability to prioritize Personal efficiency Organizational skills Willingness to delegate Ability to say "no"	Available staff, tools, and supplies Efficient labeling of specimens and samples Team huddles	Stewardship of laboratory resources Institutional efficiency of ordering and collecting the right specimens for the right test Budgeting for a sufficient number of adequately trained and educated laboratory professionals
Meaning in work	Self-awareness of most personally meaningful aspect of work Ability to shape career to focus on interests Seeing impact of work on patient care Personal recognition of positive events at work	Relationships with pathologists and clinicians Match of work to talents and interests of employee Opportunities for growth in education, research, leadership	Organization culture Recognition of value of laboratory professionals Opportunities for education and professional development
Culture and values	Personal values Professional values Level of altruism Moral compass/ethics Commitment to organization	Behavior of work unit leaders Work unit norms and expectations Equity/fairness	Organization's mission and values Balance of patient care and quality with profit Behavior of senior leaders Communication/messaging Organizational norms and expectations Just culture
Control and flexibility	Personality Assertiveness Intentionality	Degree of flexibility with vacation scheduling, bench assignments, start/end times	Policies
Social support and community at work	Personality traits Length of service Relationship-building skills	Collegiality in practice environment Physical configuration of work unit space Social gatherings to promote community Team structure	Collegiality across the organization Recognition of importance of laboratory professionals Space to relax and eat Strategies to build community Social gatherings
Work-life integration	Priorities and values Personal characteristics such as spouse/partner, children/dependents, and health issues	Work scheduled in advance Structure for emergent overtime Staffing sufficient to allow for time away Fair implementation of time away policies Expectations/role models	Vacation policies Sick/medical leave Policies allowing part-time work and flexible scheduling Expectations and role models

[a] Adapted with permission from reference 4.

include the Utrecht Work Engagement Scale and the Empowerment at Work Scale (4).

As a second strategy, leaders need to recognize that employees have different talents and different motivations. Work with physicians has shown that the ability to spend 20% of professional effort on the aspect of work that is most meaningful to the person can lower the risk for burnout (4). It is intuitive to assume this is true for other laboratory professionals (2). Although benchwork is usually the most urgent work in any laboratory, there is other work that is at least as important (if not as urgent) to the continued success of a laboratory. One aspect is education; this includes the education of students of all varieties, from medical students to clinical laboratory scientists, to medical residents and fellows of all backgrounds. Some laboratory professionals enjoy quality management or research; others enjoy working with their professional organizations; others would be excellent recruiters for the profession at high school career fairs. Some laboratory professionals want to learn data management skills and others want to develop their leadership potential. Although these tasks never seem so urgent as working the bench, they are critical to building or reinforcing the infrastructure of the work unit and the profession; they also allow each employee to find meaning and joy in work.

It is also important to understand different strengths, ways of learning, and comfort levels with cross training. Some laboratory professionals like to be cross trained in as many areas as possible and are comfortable jumping from one bench to the next. Others prefer to do a deep dive and master the knowledge of a more limited area, such as antimicrobial susceptibility testing. Both strengths are needed in a large, sophisticated laboratory.

Many laboratory professionals have not thought about the different ways in which they can grow, and many have the perception that the only way to advance in the laboratory is to give up benchwork and direct patient care and to move into supervisory or administrative roles. It benefits the laboratory management to help each employee discern individual strengths and joys, to facilitate growth in those areas, and to harness the energy for the good of the organization, the work unit, and employee.

A third strategy is to cultivate community at work (4). This has been very difficult to do during the pandemic. One strategy that has reduced burnout at Mayo Clinic is the establishment of small (six to eight colleagues) COMPASS groups (Colleagues Meeting to Promote and Sustain Satisfaction). Originally open to a randomized group of physicians, the membership has been broadened to all physicians and scientists (4). Some groups have continued meeting for over 10 years (personal communication). Another option is to establish a pleasant break area with fruit and healthy beverages, computer workstations, comfortable reading chairs, and lunch tables.

A fourth strategy is to align values and strengthen culture (4). Most healthcare organizations put a premium on serving patients and providing the best healthcare possible. Laboratory professionals are an important part of these efforts. Essentially every hospitalized patient has specimens collected and tested by laboratory professionals so that clinicians can provide the best care. Just as laboratory professionals are committed to patient care, so the organization needs to be committed to its employees, and the employees need to perceive that commitment.

A fifth strategy is to promote flexibility and work-life integration (4). Allowing laboratory professionals to choose start and end times can benefit individuals as well as provide continuous coverage and communication during transitions between shifts.

A sixth strategy is to publicize resources for resilience and self-care. These offerings can backfire, though, if employees hear a message that the burden of burnout is theirs alone, rather than a challenge to be shared among the organization, work unit, and employee. The organization needs to demonstrate that it is addressing issues contributing to employee dissatisfaction (4).

Additional Trends and Needs of Laboratory Employees

Several additional trends can influence employee needs and have ramifications in the workplace. The first trend is that questions of fairness and equity are now routinely raised (11). These questions can be applied to scheduling work as well as paid time off. Employees with seniority typically get more paid time off; should they also have preference in scheduling, or should the order of employees' choosing vacations be based on a lottery? Are raises or bonuses distributed as a flat increase or as a percentage of current salary? Should current employees receive pay equity boosts when new employees are receiving premium salaries?

A second trend is that managerial tasks such as scheduling and payroll are becoming more automated. Will this allow managers to focus less on managing tasks and more on managing employees, including their career trajectories and roles in the work unit and organization? Or will institutions reduce the number of managers, increasing their span of control (11)?

A third trend is that companies will be using wellness metrics, in addition to employee engagement surveys, to assess employees' needs. A 2020 survey of human resources executives found that during the pandemic, almost all companies made significant investments in wellness offerings, with the greatest increase in mental health benefits (11).

A fourth trend from the ASCP 2019 wage survey is that salaries are continuing to rise for most laboratory

本书版权归John Wiley & Sons Inc.所有

Table 6.2 Behaviors, strengths, and struggles of the workplace generations[a]

Generation	Organizational behaviors	Workplace strengths	Workplace struggles
Traditionalists	Embody a traditional work ethic Typically disciplined, loyal team players who work within the system Respectful of authority, patient, follow the rules Vast knowledge legacy to share Sense of obligation Observe fiscal restraint; risk-averse	Great knowledge Hard-working Stable Loyal Thorough Detail-oriented Focused Emotionally mature Strong commitment to teamwork and collaboration Strong communication skills	Reticent when they disagree Reluctant to buck the system Uncomfortable with conflict and ambiguity Reluctant to give feedback Not as comfortable with technology Prefer formality Need respect Conservative when faced with innovation
Baby Boomers	Career-oriented Tend to be optimistic, ambitious, competitive, and focused on their personal accomplishments Believe in working long hours ("live to work") and expect younger generations to do so as the path to success Comfortable in the workplace culture they created Large knowledge and experience legacy to share	Loyal to organization Have a team perspective Consensus builders, promoting group decision making Knowledgeable and experienced Efficient Service- and quality-oriented Confident task completers Accepters of diversity Effectors of change Mentors	Wary of nontraditional work styles of later generations Technology replacing human interaction Require recognition Share praise and reward Balancing work and family Uncomfortable with conflict; reluctant to go against peers
Generation X	Redefined loyalty, having seen their parents laid off or facing job insecurity Committed to their work and the people they work with rather than the company Skeptical risk takers who want fun in the workplace Seek more work-life balance ("work to live")	Well educated Independent Value learning and development of skills Practical problem solvers Comfortable with change and competition Creative risk takers Techno-literate Willing to challenge the status quo Better team workers than Baby Boomers despite being individualistic Value Lean and Six-Sigma approaches to minimize waste/non-value-added activities	Career development Independence; prefer working alone Conflict resolutions and office politics Multigenerational team projects Balancing work and family Skeptical and distrustful of authority Not overly loyal to employer Want to be challenged and provided feedback Dislike meetings
Millennials	Typically team-oriented, working well in groups as opposed to individual endeavors Expect to work hard Good at multitasking Seek balanced life Highly educated	Goal-oriented Optimistic Able to multitask Tenacious Adaptable to change Technologically savvy Driven to learn and grow Team-oriented Embracers of diversity Value training Entrepreneurial Tolerate failure well	Independent work Respectful communication Functional literacy Need supervision and structure, especially with people issues Reject the concept of "paying dues"; expect input immediately Perceived as demanding and challenging the status quo Realistic goals
Gen Z	Willingness to change jobs and career paths Believers in fairness, equity, work-life balance Alternative sources of education and training	Strong embracers of diversity Awareness of and involvement in social issues, climate change, etc. Empathy Adaptability Technology is second nature Broad social connections via technology	Personal social interactions were restricted by the COVID-19 pandemic Education options, mentoring, and skills training opportunities were negatively impacted by pandemic Deep insecurity about the future, both personal and the world Pandemic-linked stress

[a] Data from references 15 and 16.

本书版权归John Wiley & Sons Inc.所有

Table 6.3 Generational work, communication, and technology styles[a]

Generation	Work style	Communication preferences	Technology	Cultural preferences and values
Traditionalists	Want a fair and consistent approach to workplace with clear direction, expectations, and long-term goals Have strong work ethic and discipline Want to be valued for age and experience Can be a stabilizing influence, especially when teamed with Millennial employees Hesitant to disagree; dislike conflict	Prefer more formal, professional language Messages should relate to company history and long-term goals Words and tone of voice should be clear, respectful, and grammatically correct with no slang or profanity Preferred style is memos, letters, and personal notes	Many are not comfortable with technology but are willing to learn	Tend to be conservative in dress and language and in their approach to work View work as a privilege and believe in a respectful workplace Patriotic; grew up as part of the American Dream May struggle with respect for diversity
Baby Boomers	Tend to have strong work ethic, good communication skills, and emotional maturity Strong team players, insisting on being involved in decisions and influencing the direction of their organizations Uncomfortable with conflict and reluctant to go against peers May put process ahead of results	Conversations are better over breaks or meals, as they tend to see relationships and business results as intertwined Ask about mutual interests such as family Get one another's input and link the message to the team or individual vision, mission, and values Preferred style is phone calls and personal interaction	Worried that technology is replacing human interaction Worried they are being left behind	Tend to view their value as a person through their work Take democratic approach to work and value consensus Prefer a more personal approach to the workplace than Traditionalists May struggle with nontraditional working styles of younger generations, but many are now interested in more work-life balance
Generation X	Prefer to work independently and are at their best when given a goal but not told how to accomplish it Committed to work and the people they work with rather than their company Skeptical risk takers who want work to be fun Seek more work-life balance	Prefer direct and straightforward communication Because they don't want their time wasted, may seem abrupt Intolerant of business-speak; rather want clear statement of what is needed and when Preferred style is voice mail or email	Techno-literate Worried about being outpaced by younger coworkers	Independent, self-reliant, and willing to challenge the status quo May seem reluctant to give their loyalty Adaptable and thrive in midst of chaos and change Enjoy achieving measurable results and streamlining systems and processes
Millennials	Able to multitask and expect to be able to socially network at work Prefer working in teams but may need supervision and structure Reject concept of "paying dues" Expect input immediately Want flexibility to work where and when they want so they can pursue their outside interests	Want positivity Prefer text messages or face-to-face meetings Want message tied to their personal or team goals Intolerant of condescension, cynicism, and sarcasm Preferred style is instant messages, blogs, text messages, and emails	Technologically savvy; sometimes impatient with those who aren't	Very community-oriented Value diversity See the world as global, connected, and 24/7 Achievement-oriented and confident, which may appear to be cockiness Informal style may rankle some members of older generations
Gen Z	Inexperienced in the role of pupil or trainee Flexible in job and career choices May be perceived as flighty or undecided Loyalty to coworkers more than to employer	Preferred communications via technology Traditional grammar, spelling, and language are less valued	Technology is second nature	Significant proportion of personal interaction is via social media

[a] Data from references 15 and 16.

本书版权归John Wiley & Sons Inc.所有

professionals. Exceptions to this trend are the salaries for cytogenetic technologists, laboratory information systems personnel, and performance improvement/quality assurance personnel. Employees in urban areas continue to outearn those in rural areas. About 85% of employers offered medical and dental benefits, and about two-thirds offered retirement benefits, shift differential, and extra pay for weekends, holidays, and overtime. Only about a third of employers pay for tuition or continued education, and only a fifth offer flexible work hours (12).

A fifth trend, that of increasing retirements, is no longer evident in the ASCP 2020 vacancy survey. Earlier ASCP vacancy studies have warned of the loss of senior and experienced employees. The 2020 data indicate that many of these retirements have already happened, meaning that the 5-year anticipated retirement rate is decreasing. Nevertheless, the highest staff retirement rate (17.9%) was in the chemistry/toxicology laboratory, and this laboratory area also has the highest anticipated percentage (20.4%) of employees expected to retire within 5 years. The cytology section had the highest rate (43.6%) of supervisory retirements. On average, it takes 3 to 6 months to hire staff in most areas of the laboratory, except for immunology, where vacancies persist for 7 to 12 months (13).

For microbiology laboratories, the expected retirement rates in the next 5 years are 14.3% for staff and 30.9% for supervisors. Certification (MST, MLS/MT, Technologist in Microbiology, or Specialist in Microbiology) is required for most microbiology employees. Over 75% of staff and over 90% of supervisors have certification (13).

When the ASCP survey asked what laboratory employees want, the main responses were increased salaries and stronger efforts emphasizing the role of laboratory professionals for patient care (13).

The Role of Generational Differences

Mentions were made above of Gen Z and how the pandemic altered their education and entry into the work force. This group, born in 1997 and subsequent years, differs from previous generations in that their connection to the internet has been primarily through mobile devices, with assumptions of constant connectivity and entertainment on demand (14). Intergenerational differences among earlier generations, the Traditionalists (born 1928–1945), Baby Boomers (born 1946–1964), Gen X (born 1965–1980), and Millennials (born 1981–1996), were explored in the previous edition of this chapter, and two tables from that chapter are included here, with the addition of Gen Z for comparison. The current employee market no longer includes a significant proportion of Traditionalists, while Baby Boomers are in the process of retiring as well. Table 6.2 provides a summary of the behaviors, strengths, and struggles of these groups (14–16), and Table 6.3 presents a summary of their generational work, communication, and technology styles.

SUMMARY

Organizations need to prioritize burnout among laboratory employees; an ASCP survey conducted before the pandemic indicated that half of the respondents were feeling burned out at the time of the survey. The organization and work unit play a major role in burnout; combating burnout and restoring engagement are a shared responsibility.

KEY POINTS

- Eighty-five percent of laboratory employees have struggled with burnout at some point.
- Combating burnout and helping employees to become engaged again are a joint responsibility of the organization, the work unit, and the employee.
- There are tools to assess and combat burnout.
- Generation Z will have some unique challenges in entering the workforce because of the impact of the pandemic on their schooling and on the hidden curriculum of professionalism and adapting to a workplace.

GLOSSARY

Baby Boomers The generation of individuals born between 1946 and 1964.

Generation X The generation of individuals born between 1965 and 1980.

Generation Z The generation of individuals born in 1997 and subsequent years.

Millennials Also known as Generation Y, the generation of individuals born between 1981 and 1996.

Traditionalists The generation of individuals born between 1928 and 1945.

ACKNOWLEDGMENTS

Thank you to John C. H. Steele, Jr., the author of this chapter in the previous edition, for the tables on generational differences.

REFERENCES

1. **Garcia E, Kundu I, Kelly M, Soles R, Mulder L, Talmon GA.** 2020. The American Society for Clinical Pathology's job satisfaction, well-being, and burnout survey of laboratory professionals. *Am J Clin Pathol* **153**:470–486.

2. **Kroft SH.** 2020. Well-being, burnout, and the clinical laboratory. *Am J Clin Pathol* **153**:422–424.

本书版权归John Wiley & Sons Inc.所有

3. Kelly M, Soles R, Garcia E, Kundu I. 2020. Job stress, burnout, work-life balance, well-being, and job satisfaction among pathology residents and fellows. *Am J Clin Pathol* **153**:449–469.

4. Shanafelt TD, Noseworthy JH. 2017. Executive leadership and physician well-being: nine organizational strategies to promote engagement and reduce burnout. *Mayo Clin Proc* **92**:129–146.

5. Rogers DA. 1983. Stress and job satisfaction of clinical laboratory scientists. *Am J Med Technol* **49**:183–188.

6. Wigert B, Agrawal S. 2018. Employee burnout, part 1: the 5 main causes. Gallup Workplace. https:www.gallup.com/workplace/237059/employee-burnout-part-main-causes.aspx. Accessed 12 April 2022.

7. Garcia E, Kundu I, Kelly M, Guenther G, Skillman SM, Frogner B. 2021. *The Clinical Laboratory Workforce: Understanding the Challenges to Meeting Current and Future Needs*. American Society for Clinical Pathology, Washington, DC, and Center for Health Workforce Studies, University of Washington, Seattle, WA.

8. Rikleen LS. 2020. What your youngest employees need most right now. *Harvard Bus Rev*. https://hbr.org/2020/06/what-your-youngest-employees-need-most-right-now. Accessed 12 April 2022.

9. Maslach C, Jackson SE. 1981. The measurement of experienced burnout. *J Organizational Beh* **2**:99–113.

10. Demerouti E, Bakker AB, Vardakou I, Kantas A. 2003. The convergent validity of two burnout instruments: a multitrait-multimethod analysis. *Eur J Psychol Assess* **19**:12–23.

11. Kropp B, McRae ER. 2022. 11 trends that will shape work in 2022 and beyond. *Harvard Bus Rev*. https://hbr.org/2022/01/11-trends-that-will-shape-work-in-2022-and-beyond. Accessed 12 April 2022.

12. Garcia E, Kundu I, Fong K. 2021. The American Society for Clinical Pathology's 2019 wage survey of medical laboratories in the United States. *Am J Clin Pathol* **155**:649–673.

13. Garcia E, Kundu I, Kelly M, Soles R. 2021. The American Society for Clinical Pathology 2020 vacancy survey of medical laboratories in the United States. *Am J Clin Pathol* **152**:1–16.

14. Dimock M. 2019. Defining generations: where Millennials end and Generation Z begins. Pew Research Center, Washington, DC. https://www.pewresearch.org/fact-tank/2019/01/17/where-millennials-end-and-generation-z-begins/. Accessed 12 April 2022.

15. Tolbize A. 2008. Generational differences in the workplace. Research and Training Center on Community Living, University of Minnesota. https://dwashingtonllc.com/pdf/generational_differences_workplace.pdf. Accessed 12 April 2022.

16. Birkman International. 2009. How generational differences impact organizations and teams. https://birkman.com/generations-ebook/. Accessed 12 April 2022.

本书版权归John Wiley & Sons Inc.所有

7

What Is Motivation?
Leadership as a Conduit of Motivation
Knowledge of Self
Creating the Vision • Humility • Work-Life Balance and Basic Needs
Knowing What Others See in You
Factors of Motivation • The Right People Need the Right Leader • Actually Fix the Problems
Knowing the Emotions of Leading
Emotional Intelligence • The Need for Purpose • Human Motivation Theory
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES

Motivating through Intelligent Leadership

Christa Pardue

OBJECTIVES

To clarify how the natural internal motivation in people can be sparked by effective leadership

To convey that knowledge of oneself as a leader will provide an understanding of the needs of others

To illustrate through real-life stories of the laboratory how the basic principles of motivation can be applied

To energize leaders to lead

Leadership is much less about what you do, and much more about who you are.
Jim Collins, Foreword, *Hesselbein on Leadership*

What Is Motivation?

Why did I want to take on another project like writing about laboratory leadership when I have more things to do in my life than I could possibly ever get done? For the same reason that I agree to make cupcakes for my daughter's third-grade class when I know that I will not be flying back into town until 8:00 the evening before. It's because of my strong passion and interest, or motivation, for these two aspects of my life. It's that same strong motivation that drives me toward my professional obligations. It's the striving to be a productive member of the profession and the need to promote the profession of clinical laboratory medicine, but even more, it's the desire to add to society by supporting the healthcare needed by our community. Ultimately, for healthcare leaders, the question becomes, how do we continuously ignite this type of motivation in the people around us whom we depend on most to provide this care? I would state that the answer lies in the leader's intimate knowledge of him- or herself.

The goal of this chapter is to take the basic theories of motivation and apply them to real-life settings in the laboratory by relating some experiences that I have had during my tenure in the profession. Everyone can read these theories on their own, but often it's the real-life application of the theories that challenges us. It's my intent to make these management theories real and applicable to laboratorians. If my limited experiences can help, I welcome you to them.

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch7.

本书版权归John Wiley & Sons Inc.所有

Leadership as a Conduit of Motivation

While this chapter is focused on motivation, leaders assist people to harness their internal motivation to be successful, productive team members. The very definition of a leader is one who establishes a vision and direction, removes barriers, and assists others in growing towards that vision.

Knowledge of Self

Creating the Vision

Understanding oneself as a leader will provide clarity in communicating one's purpose or direction and the reason why that direction is appropriate. Leaders must possess the ability to define a vision and design a path to achieve that vision. Knowledge of why you as the leader defined the vision in the first place is the same knowledge that will motivate others to follow it. I think of the time when my administrator sent me an email asking me how much a particular point-of-care test cost. I hesitated to answer, assuming that the next question was going to be "Can you bring it into our emergency department?" I answered with all kinds of reasons why we didn't want to do that, citing coefficients of variation, training, and costs. I took the whole day designing the perfect rebuttal email. I later found out that he had actually asked the question because he was demonstrating the costs our laboratory had avoided by maintaining exceptional turnaround times with the laboratory-based test and therefore preventing the need to bring in this point-of-care test. My original mistaken belief in his motive prevented me from fully buying into his question. Once I realized his purpose, I was motivated to give him more data than he needed. As it turned out, he was trying to brag about our team; I'll take that any time I get a chance. This example may seem somewhat superficial; let me move toward a deeper concept of knowing my own motives for creating a vision.

Frequently, one vision is a stepping stone to another goal. Some years back, like many laboratories, our laboratory underwent a total process flow transformation using the Lean concepts. The intent was to produce rapid turnaround times for the emergency department. With this project, the laboratory did align the turnaround times within the expected goal; now consider the advantage in adapting to the now more global picture for those who have already experienced some form of adaptation to more efficient methods. As initiated by the U.S. Department of Health and Human Services, "AHRQ is the lead Federal agency investing in research to improve diagnostic safety and reduce diagnostic error" (1). Any previously accomplished efficiency effort has provided a head start toward meeting these requirements or any other unforeseen shifts in demand. This vision ultimately provided a stronger position for the organization when weathering the storm of the coronavirus disease 2019 (COVID-19) pandemic. The agility instilled in laboratorians through Lean/Six Sigma workflow demands made it possible for laboratories to survive the sudden shift in priorities while testing needs for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) grew exponentially. As leaders, laboratory managers must ultimately know the purpose of the vision that they design and continuously refresh the communications about that purpose. For our laboratory, team knowledge of the total impact has continued the motivation to sustain the Lean principles and maintain the efficiencies gained by the process changes.

Humility

Moving to a more obvious concept of leadership and its impact on motivation, it must be recognized that as a leader, it is your own behavior that affects others. "Model the behaviors you hope to see" (2). Consider those days when issues with productivity, regulations, and compliance challenge your own motivation to keep trying. I sometimes get into a "rut" or emotional low spot when it seems that everything is impossible. I remember that with one of our first productivity challenges, my reaction was not positive. I remember saying things like "This is impossible," "We can't do this," and "We already benchmark as one of the most efficient laboratories," and my reactions immediately informed the opinions and beliefs of the managers and staff who reported to me. Their faces dropped when I looked up from that productivity report in my hand. They were completely fueled to fight this battle beside me and aware that arguing the obvious was not the answer. My emotional reaction had immediately created a negative perspective toward this challenge, and now how would I take this back? How, at this point, would I motivate these folks I depended on most to accept this challenge and conquer it?

In considering the leadership principles conveyed by Jim Collins in his article "Level 5 Leadership: The Triumph of Humility and Fierce Resolve" (3), I knew that at this point, the best answer would be for me to admit to them that I had reacted emotionally rather than responding appropriately to the challenge. As Collins describes leadership in this article, in addition to acquiring all of the other basic leadership skills, a leader also needs to know when to be humble. It's important to acknowledge to those you lead that you too can make mistakes and that you too need them to be understanding and accepting of the human side of their leader. It is also through your acceptance of your imperfections that your team will learn that it is appropriate to be humble and recognize weakness in themselves, with a personal motivation to grow and improve their own faults. This will set the example to be motivated to improve one's own performance.

本书版权归John Wiley & Sons Inc.所有

Work-Life Balance and Basic Needs

Looking at motivation in terms of Maslow's hierarchy of needs, as illustrated in the book *Maslow on Management* (4), leaders must consider how they themselves fall under the requirements for fulfilling their own basic needs. "It's easy to get so wrapped up in building the company that you lose sight of what's really important in your life and why you have your company in the first place" (5). Leaders often put too much of themselves into their job and do little for themselves or their home life. This will cause a lack of compassion for the basic needs of the people around you. Sustaining a reasonable life outside of work will help the leader to understand the needs of the staff. Just recently, I saw my son play T-ball for the first time. It gave me chill bumps to think that my baby was becoming a big boy and that I was there to see it. It's this very realization that allows me to see why my staff ask for time off to coach Little League, or prefer not to work overtime too often, or would like to know their schedules in advance. It's so that they can plan to attend the things in their life that mean this much to them. Our laboratory has always taken a stance that, if at all possible, we will grant all time-off requests. The staff understood that vacation requests were no longer a competition, but a collaboration. They realized that if they helped us to make this happen, time-off requests would always be granted even for themselves. It was often a struggle, but we worked together and went 6 years before we had to deny a request for time off due to inability to find a way to cover the work area. Because of this, call-ins are very rare and the fear of rejected vacation requests is no longer a worry among the team. This is exceptionally necessary when staff are at high risk of burnout. COVID-19 certainly made this a reality, with heightened staffing issues and quarantines. In today's environment, with the pandemic and the Great Resignation, control has shifted to the workers, making it even more critical to provide a work environment that is conducive to meeting the staff members' personal needs. It was an understanding of how the fulfillment of my needs for both work and life motivated me that allowed me to see what would motivate the people around me.

Knowing What Others See in You

Factors of Motivation

Based on the theories of motivation described by Frederick Herzberg (6), motivation can be created by a desire for achievement, recognition, or accomplishment; increased responsibility; opportunity for growth and development; or creative and challenging work. I relate these needs back to goal setting. If people have reasonable and obtainable goals and are enabled to accomplish them, they have the potential to achieve the factors described by Herzberg. An effective leader will collaboratively set goals with those involved in the work based on the vision of the organization and then enable those people to use their abilities to accomplish the goal. One of the factors of motivation theory is that motivation is driven by accomplishment and recognition. Last year our laboratory designed a type of achievement award that is sort of a "most valuable player" award for the year. We hold a recognition ceremony during National Medical Laboratory Professionals Week where we recognize the winner of this award. It is based on the staff member's achievements over the past year, but more importantly, it is based on the ability of the staff member to design and implement a process, technique, or technology that will meet their goal. "Motivation to contribute has to be matched with ability to contribute" (7). Again, a leader must recognize that it is important to assist in setting the goal but also to enable the person to achieve the goal using methods that he or she designs. Enable people to achieve, accomplish, and grow, and then recognize the achievement (7).

The Right People Need the Right Leader

One of the strongest lessons I have learned as a laboratory manager is that having the wrong people in place will greatly affect the motivation of those around them. "You de-motivate people if you have the wrong people, because there's nothing that the right people hate more than having to carry the weight of people who aren't carrying their weight" (5). From the standpoint of leadership, this is demonstrated in a leader's ability to hold everyone to the same level of expectations. Most importantly, leaders must hold themselves to the same or higher level of expectations. One of my first managers told me, "Never ask anyone to do something that you yourself wouldn't do." Personally, I find it is important to maintain my skills as a bench technologist, and I encourage all of the laboratory managers who report to me to keep abreast of the bench-level work. Not only does it allow me to make better-informed decisions, but it also shows our team that we are all in this together. Even though they joke with me and say I "look funny in a lab coat," when I work on the bench, it shows my commitment to the vision and my diligence to achieve the goal. Leaders who demonstrate a base competence or understanding for the frontline work will be respected and will be effective at motivating the people around them.

I remember a time when my bench experience worked out for our laboratory. One of our flow cytometry technologists called in sick on a day when the two other trained flow cytometry technologists were also not available to come in for very serious reasons. Being a flow cytometry technologist myself, I said, "Well, it looks like it's me today." I grabbed a lab coat and worked the entire day back on the bench. Now, a lot of managers have done that, but the point

本书版权归John Wiley & Sons Inc.所有

of this story is found in the conversation that occurred at the end of that day. One of our technologists came to me to say, "Thank you. Today, it wasn't about the work that you did but about the commitment. You showed us all that you are in it until the end. It looked like everybody worked harder today." It was significant to me that they actually noticed that they were working harder.

Actually Fix the Problems

Have you ever heard, "It doesn't matter what I say; they never fix anything"? Our hospital promotes the practice of leader rounding. I have been doing this for many years, and I remember the first few times that I spoke with some particular staff members. The answer was always that everything was fine. The more that I pursued their true opinion, the more I was told that it didn't matter. It took some time for me to prove that what they had experienced in the past was not going to remain true. I can think of one issue in particular that we dealt with years back. We were failing to call some critical results. The further we investigated it, the more we heard from our staff. We soon realized that the reason we were missing them was that half of the critical limits were set as prompts in our laboratory information system (LIS) and the other half were not. We were depending on our extremely busy technologists to know when a critical result came over their LIS screen or to check a manual chart for each result, and worse yet, they had to do that only half of the time. I promised them that we would fix that, and we did. We spent the time to get all critical values in our LIS. It was a relatively easy fix that had a major impact on our patients and staff. We were able to guarantee our technologists that if a result fell into the critical range, the LIS would always prompt them. We quickly got to a 100% critical call rate and have sustained that for years now. Once the technologists realized that we were serious about fixing problems and making their work easier, they started sharing all of the "frustraters" in their job.

We took them all seriously and fixed everything that we could, but more importantly, we explained why we couldn't fix the remaining problems immediately. As we continue to deal with the severe shortages in the supply chain, we see that this situation is global and not within our direct scope to correct, but we owe it to our peers to communicate what efforts are under way to help with the supply shortages. In his book *Arriving Today* (8), Christopher Mims reviews the almost overnight impact on the global supply chain that the COVID-19 pandemic had. "It became clear that three in four firms would have their supply chain disrupted in some way." It is essential for those within and outside our authority to understand that every effort possible is being utilized to reduce their struggle with supplies. Providing cross-references for alternate supply options, expanding portfolio access, and publishing conservation techniques are just a few of the many attempts to provide some relief with this issue. The most essential part of these efforts is communicating with those impacted and making certain that they know they are supported.

Knowing the Emotions of Leading

Emotional Intelligence

The ability to consider emotions and feelings to enhance thought, also known as emotional intelligence, as described in the theories of Daniel Goleman in both his book titled *Emotional Intelligence* and the article titled "Leadership that Gets Results" (9, 10), is widely considered in leadership training. In the book *Leadership in Healthcare: Values at the Top* (11), Carson Dye discusses how healthcare leaders must recognize their own values in order to understand their own behavior and thoughts. Healthcare is a demanding field. With pressures to meet productivity standards, cut budgets, and improve quality, every healthcare professional is feeling the increase in stress. This is best stated by Brenda Freshman and Louis Rubino in their article "Emotional Intelligence: A Core Competency for Healthcare Administrators": "Health Administrators must contend with providing quality service to their customers during a period of limited fiscal and human resources" (12). As leaders in laboratory medicine, we must recognize that the pressure of meeting these tighter expectations carries over all levels in the department. In the past year, I have seen many technologists reach their capacity for stress overload. As an example, at one point we had been looking for an evening-shift technologist for nearly 10 months. I was so bogged down in setting up interviews, trying to recruit, and talking with anyone who might have a lead that I failed to "look up" and notice the folks who were getting the work done with a reduced staff. They were getting it done, but as the months went by, they were getting worn and tired. They were covering multiple shifts and extra weekends to make up the difference, and while I was continuously working to try and fix their problem, I had not taken the time to reassure them that I was working on it. They needed to know that I recognized how much they were giving in order to get the work done. In this case, I let the stress of finding someone block me from taking the few minutes to care for our folks who were trying so hard.

Freshman and Rubino also point out that many healthcare administrators have a "misconception that the compassion that drew them to the industry will serve them well as they lead their organizations" (12). Compassion to care for the physical well-being of a patient does not always bring compassion or the realization for the need for compassion for those who are not patients. When it comes to our coworkers, we would always care for them when they are sick, but we don't always recognize that care goes beyond their sick days and into every interaction that we have with them. Sometimes we are so busy caring for our

本书版权归John Wiley & Sons Inc.所有

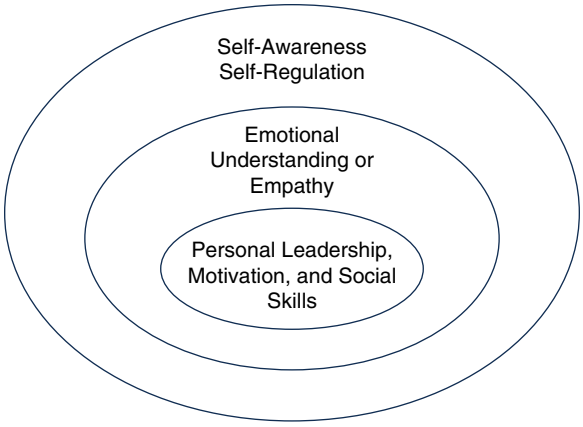


Figure 7.1 The onion of emotional intelligence.

patients that we forget we are all customers of each other. What good have we wrought if while healing one person we hurt another? With that outcome, we are still a person down. We need to learn to heal everyone we come in contact with. Goleman (9) lays out five components of emotional intelligence (see Fig. 7.1): self-awareness, self-regulation, motivation, empathy, and social skills. I recently received a phone call, as a result of which I didn't get what I was asking for and was angry about it. I recognized that being angry wouldn't change the caller's mind, but I knew that it was an emotion that I had to experience in order to get over it. I decided that I would allow myself to be silently angry for a couple of hours but then I had to get over it, as no one wins every battle. I have seen situations in which others reacted differently and proclaimed a full-out war every time they lost a battle. I believe it is through self-regulation that I chose to lose battles and stay away from wars, but I also believe that this level of self-regulation helps me to motivate those around me. The ability to intelligently control your own emotions will allow you to react appropriately as situations come up. Others will see that you always stay calm and react well. Understand that everyone gets disappointed or frustrated, but reactions due to anger should not happen.

While I have no intention of reviewing all of the components of emotional intelligence, I do think that for the purposes of motivation, it's essential to discuss the component of *self-motivation*. Self-motivation is drive, positivity, and passion to achieve. I maintain my self-motivation by watching the company I keep. Nothing brings me down more than to be around someone who finds something wrong in everything. I have also noticed that these types of people like to feed off of the motivation that you generate in yourself and walk away from you having taken all of the energy that you had. Be prepared for these encounters, as it seems that such individuals seek out self-motivated people to feed on. If these people work with you, and I'm sure everybody has some, try to control your encounters with them so that they occur at times when you feel strong enough to stay positive even after the encounter. Keep your encounters on task for the purpose, and once the purpose is accomplished, move on. Don't allow them to drag you into a conversation that has no value, and always be prepared with positivity to add in every encounter. A truly self-motivated person has the strength to overcome negativity. Eventually the self-motivated person will either displace the negativity with positive motivation or, at the very minimum, will no longer be "fun" for the negative person to interact with. Don't let them feed on you.

The Need for Purpose

Purpose is a natural human need. "We want to feel that our lives have a deeper meaning that goes beyond paychecks and discount shopping…. Once our physical needs are met, we long for love, belonging, esteem and finally what Maslow called 'self-actualization'—that our lives count" (13). A purpose-driven leader is one who can clearly define and communicate the purpose of the direction. As Maslow describes the need for self-actualization, it becomes clear that we all naturally need a purpose for existence. Leaders in healthcare often assume that "patient care" is our purpose, but while it surely is our overall global purpose, it is not specific enough to define how all work processes relate back to that purpose. Consider the need for a hospital-based laboratory to operate an outreach program. The nature of a hospital's acute-care needs requires redundant equipment in the hospital laboratory to prevent any potential downtime in critical testing. This redundant equipment often runs well below capacity. A hospital outreach program offers an opportunity for the hospital to maximize the productivity of its existing laboratory services by utilizing the excess capacity of the redundant equipment and provides a volume boost that may permit lower pricing tiers when negotiating for new equipment and lower operational reagent pricing. Ultimately hospital outreach programs help the organization to run more efficiently, but also, for nonprofits, the extra income goes back into the hospital capital budget and allows the hospital to purchase the capital equipment required throughout the hospital to care for patients. In the end it goes back to patient care, but up front it is often misconceived simply as a revenue source for hospitals rather than a cost saver for the hospital's already required laboratory needs and a means to provide capital funding for all areas of the hospital. The simple knowledge of the purpose of a laboratory outreach program has motivated many administrators to start such programs but has also motivated laboratory staff to provide the service needed to maintain a sizable client base.

It is also important to demonstrate how each position contributes to the overall purpose. Purpose-driven employees need to know that they are contributing.

本书版权归John Wiley & Sons Inc.所有

We run a fairly strong outreach program in which a few people are responsible for receiving the courier deliveries. This includes registering the "nonpatients," ordering the tests, and dispensing the specimens to the appropriate testing areas. We formed a committee designed specifically to review and work on the laboratory write-offs. This committee involved staff from revenue management, registration, and laboratory, including outreach staff. It was clear that a large portion of write-offs were outreach specimens. By bringing this awareness and purpose to the laboratory staff and involving laboratorians in this revenue cycle, we were eventually able to cut our laboratory write-offs by 75%. It took time and work, but most importantly, it took the motivation of the outreach staff to develop methods of confirming compliance at order entry that ultimately had the biggest impact. To this day, our continued diligence maintains this rate. We still meet regularly and refine the purpose to keep the awareness up and the write-offs down.

Human Motivation Theory

David McClelland (14) proposes in his human motivation theory that people can have one of three dominant motivators (Table 7.1). As part of this theory, McClelland describes what is referred to as an *achievement* motivator. He describes people who respond to this motivator as having a strong need to set and accomplish goals, a willingness to take risks to accomplish goals, and the need for consistent feedback on the progress of their goals. Effective leaders must have a mechanism to set goals, measure progress toward those goals, and eventually accomplish the goals they set. "Goal theory assumes that goals are cognitive representations of what individuals are trying to accomplish and their purposes or reasons for doing the task" (15). Goals are set by leaders and staff in collaboration, with consideration of the mission. In laboratory medicine, it is often seen that goals include things like specified turnaround times, efficiency rates, and customer service goals. Goals for laboratories could also include new instrument implementation or project deadlines. Setting reasonable, obtainable goals that can be measured will drive the motivation to achieve these goals. Our experience with a project to implement a specimen-tracking system demonstrated many facets where goal setting enabled this project to be a success. The project involved three different areas within our organization in addition to the vendor. Each group had steps that had to be completed. These steps included network line installations, facility modifications, and vendor installations. Each step was dependent on another. In order to initiate motivation on all sides, goals for accomplishment were set each week at a project meeting. The goals were measured each week and the next steps were issued. Every group in this project stayed on task and the implementation has gone well.

Table 7.1 The three dominant motivators in McClelland's human motivation theory

Achievement	Affiliation	Power
Strong need to set and accomplish goals	Need to belong	Need to control
Willingness to take risks	Need for friends	Need to win
Need for consistent feedback	Feedback should affirm trust	Feedback should be opportunities

A second part of the human motivation theory discusses the need for *affiliation*. Persons with this dominant motivator have the need to belong. They want to be liked and will concede to the group's opinion. People who are motivated by affiliation do not take risks. These people need to know that you, as a leader, like them and trust them. It's important to remember that they work in order to ensure that you continue to like them. You must make certain that you recognize their efforts by showing that you care about them. It is also suggested that with affiliation-dominated people, you recognize them privately, as they do not like to be singled out.

The third and final part of this theory refers to a dominant motivator of *power*. Persons with this motivator are the ones who want to control and win. They thrive on status and recognition and love to be challenged with a goal. We have all dealt with a person who must be in control. According to the human motivation theory, a leader who recognizes this can use it to his or her advantage. Sure, give the praise; give recognition, as long as they get the work done. Allow them to be "in charge," give them strong goals, and recognize them by allowing them to grow their career.

SUMMARY

Motivation is defined by the online *Merriam-Webster Dictionary* as "the act or process of motivating or the condition of being motivated" (16). By definition alone, motivation is considered an induced characteristic. Whether it is your self-motivation or the motivation that you fuel in someone else, motivation requires effort to sustain. It is work. There are many management theories that support the methods of motivation, but overall, it is the practical application of those theories that makes the difference. There is no better place to apply those theories than to oneself. No one can be motivated by an unmotivated person. Most people who leave a job leave their managers, not their jobs. Become motivated in yourself. Put the work into building the strongest motivation in yourself, and you will then understand what it takes to motivate others, as we are all human beings with the same basic needs. According to W. Edwards Deming, "Long-term commitment to new learning and new philosophy is required of any management that seeks transformation. The timid and the fainthearted, and the people

本书版权归John Wiley & Sons Inc.所有

that expect quick results, are doomed to disappointment" (17). Understand that becoming motivated and, more so, staying motivated is hard work, and just as with any hard work, you get out of it what you put into it.

We are currently in a perpetual state of "do more with less." As a leader in a laboratory, it is very easy to get overwhelmed in the crises and tasks that try to consume our day, but we must stay focused on our basic responsibilities as leaders. We must not let ourselves get overwhelmed, and we must get organized so that we can spend time enhancing our leadership skills. I recommend finding the time to attend leadership training classes, not because you don't know the information but because it will serve as a renewal or affirmation of the skills that most leaders already have but tend to lose when focusing on the pressures to produce billables. Use this time to reinvigorate or motivate your leadership skills. Reigniting the motivation in you to lead will produce motivation in those whom you lead.

KEY POINTS

- Motivation requires effort.
- Motivating those around you is your job.
- You must always work at developing your leadership skills.

GLOSSARY

Attribution theory The ability to look into the reason for an occurrence and adjust one's behavior accordingly.

AHRQ Agency for Healthcare Research and Quality.

Effort The only internal and variable cause to which one can attribute success or failure. It is the variable that most often makes the difference between success and failure.

Goals Specific, measurable, attainable, relevant, and timed (SMART) providers of direction.

Hawthorne effect The proven, positive effect that attention and feelings of importance have on production.

Hygiene factors Tangible, physiological factors whose absence causes employee dissatisfaction but whose presence does not create satisfaction (e.g., salary, working conditions, benefits).

Job enrichment The deliberate upgrading of responsibility, scope, and challenge as they apply to a position, title, or employee.

Level 1 Leadership "Makes productive contribution through talent" (3).

Level 2 Leadership "Contributes to the achievement of group objectives" (3).

Level 3 Leadership "Organizes people and resources towards the effective and efficient pursuit of predetermined objectives" (3).

Level 4 Leadership "Catalyzes commitment to and vigorous pursuit of a clear and compelling vision; stimulates the group to high performance standards" (3).

Level 5 Leadership A level of leadership that includes the four basic levels plus humility and will.

Motivation Internal and external factors that stimulate desire and energy in people to be continually interested in and committed to a job, role, or subject and to exert persistent effort in attaining a goal.

Motivators Internal factors that relate to the nature of work and the egos of employees. If properly addressed, these factors can create employee satisfaction (e.g., recognition, appreciation, and self-actualization).

REFERENCES

1. **U.S. Department of Health and Human Services**. November 2021. Diagnostic safety and quality. Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, Rockville, MD. https://www.ahrq.gov/topics/diagnostic-safety-and-quality.html. Accessed 1 January 2021.

2. **Schwartz T.** 23 November 2010. Leadership begins at home. Harvard Business Review Blog Network. http://blogs.hbr.org/schwartz/2010/11/one-of-the-greatest-gifts.html. Accessed 22 November 2021.

3. **Collins J.** 2001. Level 5 leadership: the triumph of humility and fierce resolve. *Harv Bus Rev* **79**:66–76, 175.

4. **Maslow AH**. 1998. *Maslow on Management*. Wiley & Sons, Inc, New York, NY.

5. **Collins J**. 1996. Looking out for number one. www.jimcollins.com/article_topics/articles/looking-out.html. Accessed 2 January 2022.

6. **Herzberg F, Mausner B, Snyderman BB.** 1959. *The Motivation to Work*, 2nd ed. John Wiley, New York, NY.

7. **Werhane W**, **Royal M**. 2009. Engaging and enabling employees for company success. *Workspan* **52**:38–43.

8. **Mims C.** 2021. *Arriving Today*. Harper Business, New York, NY.

9. **Goleman D.** 1995. *Emotional Intelligence*. Bantam Books, New York, NY.

10. **Goleman D.** 2000. Leadership that gets results. *Harv Bus Rev* **78**:78–90.

11. **Dye CF**. 2000. *Leadership in Healthcare: Values at the Top*. Health Administration Press, Chicago, IL.

12. **Freshman B**, **Rubino L**. 2002. Emotional intelligence: a core competency for health care administrators. *Health Care Manag (Frederick)* **20**:1–9.

13. **Karlgaard R.** 23 July 2009. Purpose-driven leadership. Forbes. www.forbes.com/2009/07/23/bmw-hy-vee-karlgaard-intelligent-technology-leadership.html. Accessed 2 January 2022.

14. **McClelland DC**. 1961. *The Achieving Society*. D. Van Nostrand, Princeton, NJ.

15. **Pintrich PR**. 2000. An achievement goal theory perspective on issues in motivation terminology, theory, and research. *Contemp Educ Psychol* **25**:92–104.

16. **Merriam-Webster**. 2023. Motivation. https://www.merriam-webster.com/dictionary/motivation. Accessed 30 August 2023.

17. **Deming WE**. 2000. *Out of Crisis*. MIT Press, Cambridge, MA.

本书版权归John Wiley & Sons Inc.所有

8

Effective Communication

Marianna Hofmeister

Introduction
Channels of Communication
Formal Channels of Communication • Informal Channels of Communication
Types of Communication
Oral Communication • Telephone Communication • Written Communication • Online Presentations • Electronic Communication • Visual Communication • Body Language and Other Nonverbal Communication
Barriers to Effective Communication
Physical Barriers • Nonverbal Barriers • Verbal Barriers • Psychological Barriers
The Importance of Listening
Effective Listening • Ineffective Listening • Stages of Listening • Types of Listening
Elements of Effective Face-to-Face Communication
Skills for Effective Face-to-Face Communication • Organizational Climate • Using Body Language • Using Positive Language
Leadership Essentials for Improving Communication
The Interaction Process • Adapting Communication Styles
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENT
REFERENCES

OBJECTIVES

To describe the process of effective communication

To help the reader to select the communication technique appropriate for a situation based on the advantages and disadvantages

To explain the necessity of using positive language when communicating orally and in written form

To review the necessity of fostering and nurturing a climate that supports effective communication

To discuss how to integrate the six W/H (who, what, when, where, why, and how) points effectively when disseminating information

To describe the types of listeners and explain the benefits of active listening

When people talk, listen completely. Most people never listen.

Ernest Hemingway

Communication is the exchange or sharing of thoughts or information between one person and another. Effective communication is well planned and well executed and results in the information sender and recipient sharing the same understanding of the message. Communicating professionally and personally is an integral part of everyday life. Ineffective communication is at the root of many problems, conflicts, mistakes, or misunderstandings. Business consultants and counselors confirm that communication is the number one problem in most workplaces and interpersonal relationships (1). Not all information is received or understood as intended. Even though communication problems in organizations may never be eliminated, they can be reduced significantly through ongoing awareness and skill development.

The ability to communicate effectively is essential to leadership and vital to every organization and manager. Communication skills can be learned, cultivated, and improved. Managers communicate in most aspects of their work and develop into strong leaders in part by learning effective communication strategies. Communication skills are important when creating guiding principles, interpreting policies and regulations, enforcing procedures, delegating responsibility and authority, interviewing job applicants, and managing staff. Three points make up the basic communications cycle.

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch8.

本书版权归John Wiley & Sons Inc.所有

1. *Initiation*. The sender conveys a clear, straightforward message.
2. *Message receipt*. The receiver(s) gets the message and confirms that the message is understood.
3. *Closing the loop*. The sender verifies that the message was received and understood in the manner intended.

This chapter will help the reader understand how people communicate and suggests ways to adapt their own communication style to increase understanding, build rapport, and improve workplace culture.

Channels of Communication

In organizational networks, there are distinct formal and informal communication channels. Channels carry messages from a person or group to others and disseminate information within the organization. Information flows downward, upward, and laterally and builds workplace culture.

Formal Channels of Communication

Formal communication channels are typically aligned with the organizational chart and follow organizational hierarchy. Strict lines of authority are usually followed: upper management (i.e., senior medical, operations, and administrative staff) to direct supervisors to staff.

Downward communication is commonly referred to as flowing from the top down and is primarily directive in nature. Top-down communication is used extensively by management to state objectives, disseminate new policies or policy changes, provide directives, and convey general information to subordinates. There is the possibility of dilution, filtering, or distortion of information between the original sender and the ultimate receiver, which may cause the message to be inaccurate and ultimately misunderstood. This is especially true of strictly oral communication when many levels of authority are involved. The more people involved in the downward chain, the greater the chance of ineffective communication.

Upward communication flows through the ranks from staff to upper management. Upward communication is used to convey information and provide reports. Better managers encourage a free flow of upward communication as a feedback mechanism to determine whether a message has been received, understood, and produced the intended outcome. Staff provide information and ideas to managers who value staff input and act on the information provided. Lack of upward flow or management receptivity leads to staff frustration, destroys their desire to contribute positively, and may cause them to seek different, more receptive audiences or to seek employment opportunities elsewhere.

Lateral communication flows among persons on the same level in an organization. Lateral communication encourages the exchange of information among people with similar responsibilities working on common objectives, builds collegiality and confidence, increases job satisfaction, and fosters interlaboratory (i.e., diagnostic labs to external stakeholders like public health), intralaboratory, and interdisciplinary information sharing.

Informal Channels of Communication

Informal channels operate at every level and in every department within organizations. The main informal channel is often referred to as the grapevine. This results from casual social interactions between people making sense of the continual flow of work-based information. The grapevine is constituted of live and virtual interactions and often includes individuals' reactions to new information in knowledge-based environments. As suggested by the name, information shared on the grapevine can get twisted and grow far from the original plant.

The skilled manager acknowledges the grapevine and stays attuned to the themes of the messages being shared. While some grapevines exclude managers, better managers stick to the facts, nurture rapport with employees, and ensure staff are provided with regular opportunities for feedback to minimize the negative potential effect. Conducting regular meetings with teams and individuals, providing genuine, caring support to encourage better workplace relationships, and leading by example are ways better managers work within fast-paced, challenging workplace environments to improve workplace culture.

Types of Communication

Different types of communication, including oral (face-to-face or by phone) and written (electronic or not) communication, are used in different situations and for different purposes. Face-to-face live or electronically mediated communication enhances the understanding of the audience, who benefit from seeing the communicator's gestures. Similarly, the speaker benefits from seeing the audience's facial expressions and can adjust their delivery based on what they see. These types of communication are not mutually exclusive. An initial message is often transmitted orally and followed up by a written communication. Research tells us that most of management's time is spent speaking and listening and less time is spent reading and writing (2) and that managers spend between 50 and 80% of their total time communicating (2). The use of online meeting software such as Zoom, Skype, and Microsoft Teams increases access to audiences across organizational locations and sites. The choice of communication methods varies according to the style of the sender, the situation, the audience, and the content of the message. Communication situations must be considered thoughtfully before deciding how to communicate the information to the intended audience.

本书版权归John Wiley & Sons Inc.所有

Oral Communication

Speaking is immediate and often preferred to written communication. Because the audience can seek clarification and ask questions, better understanding may be achieved in a timely way using this method. In-person communication may provide the opportunity for immediate feedback. Since nothing may be written down, permanence is lost, and the receiver cannot "revisit" the actual words used. The speaker's delivery may be suboptimal; that is, it may include mumbling, speaking too fast or too slowly, mispronouncing words, speaking in a monotone, and using distracting sounds such as "er" and "uh." However, most communication is delivered in this way, either in person or electronically.

A spoken message has three elements: verbal, vocal, and visual (3). The verbal elements are the actual words used; the vocal elements include the tone and intensity of the speaker's voice; and the visual elements incorporate everything that the listener can see. Dynamic visual, nonverbal communication grabs and holds the listener's attention and may be the most powerful element. Once the speaker hooks the listener's attention, compelling vocal and verbal elements transmit the message. The vocal elements are processed before the actual words are heard and translated, so if vocal sounds detract in any way from the meaning of the words, people may react to them and misunderstand the message (3). Because visual and vocal elements are noticed before the actual words are spoken, better speakers harmonize their appearance, vocal tones, and message. Strong messages delivered clearly using convincing words in an unwavering tone are well understood.

Telephone Communication

The telephone is a primary communication tool used in the workplace. The caller's first impression is made simply by their tone. On the telephone, there is no visual contact and consequently no nonverbal cues from body language to help the caller better understand and connect with those on the receiving end. Courtesy ranks highest on the telephone etiquette list. The caller states their name and verifies the identity of the person on the other end of the line, while being personable, to build rapport and trust with the other. Be aware that demeanor affects the tone. Sounding upbeat helps set a positive tone and makes the receiver feel more receptive. Tone often has more impact than the actual words (4). Concise, purposeful, friendly conversations are generally appreciated.

Written Communication

Written communication provides a permanent record to which the sender can refer to ensure that the message sent is correct and to which the receiver can refer as needed. When constructing a written message, the sender considers format, content, and style.

Business letters are used when contacting people outside the organization. Letters provide a long-lasting record that can be referred to as necessary now and in the future. Business letters are clear, courteous, and concise and tend to be composed of three paragraphs on a single page. Well-written business letters follow the rules of written English and demonstrate clear thinking while being respectful. Organizations typically have rules about when to use letterhead and when use of official letterhead is not sanctioned for managers.

Written memoranda, or memos, tend to be used within organizations. Memos should be purposeful, organized, coherent, and not open to multiple interpretations (Table 8.1). Memos facilitate and accelerate internal information sharing. They can be used to provide instructions, seek information or action, and to announce or clarify new policies and procedures. Memos provide a simple method to broadly communicate a message to multiple recipients. Though concise, memos may use headings, sentences and short paragraphs, or bullet points, as well as boldface and italics.

Correct spelling, punctuation, and grammar are essential elements of all types of written communication and project an image of the writer and the organization. Rereading documents and using electronic editing tools such as "Editor" in Microsoft Word (which checks spelling, grammar, and conciseness) prior to sending improves the correctness of written communication.

To ensure consistent quality in their communications, organizations are well advised to define the parameters of the use of these tools, specify the ways in which different communication options are to be used, and adopt a style guide to ensure that their preferences are implemented (5).

Online Presentations

Microsoft's PowerPoint is a widely used presentation tool and is frequently used in the workplace to communicate information during meetings (6). There are many courses on how to use this and other presentation tools, such as

Table 8.1 Writing guide for memos

Take the time to craft clear, concise, complete memoranda.
Ensure that your written messages are organized, coherent, and not open to multiple interpretations.
Anticipate questions the recipient(s) might ask.
Cover the 5 Ws and an H (who, what, when, where, why, and how). The memo should address who needs to be involved, what action is being conveyed or needs to be accomplished, and when and where the action needs to be completed. The memo should include why the memo is being written and suggestions on how the action is to be completed.
Make memoranda easy to read from a visual layout point of view.
Avoid sending mixed messages.

本书版权归John Wiley & Sons Inc.所有

Prezi, Keynote, Google Slides, Zoho Show, Canva, and Visme, and when properly used, they can be compelling business tools. These tools do not design or deliver presentations; rather they help users organize information for audience consumption. The presenter makes decisions about which tool to use depending on the purpose of the presentation, the audience, the message, and practical considerations related to delivery and sharing (Table 8.2).

Content is the most important consideration. Create an outline first, reflecting on the goals of the presentation and what points need to be covered to meet your needs (7). As communicators widely recommend, "Tell them what you're going to tell them, deliver the presentation, and then tell them what you told them." Be selective about which information to include to create a comprehensive, coherent argument that includes current, correct information and answer the "so what?" question for the audience.

Critics of PowerPoint have claimed that it promotes passive engagement by displaying information in a fragmented way that dilutes content, weakens analytical reasoning, and corrupts statistical data. It follows that when more thorough explanations or complete sentences are necessary to comprehend relationships between complex ideas, other tools may more effectively communicate the content. Reports, technical documents, and comprehensive graphs shared as printed handouts can more efficiently and accurately display complex information (6). In this type of situation, presentation software might be used to summarize information or stimulate a discussion once the technical documents and graphs have been read by the audience. Presentation software supports the speaker, enhances the understanding of audience members, and provides written documentation that may be referenced later and by other interested parties.

Table 8.2 Effective PowerPoint communications

Keep the design simple. Maintain a consistent visual theme. Use your organization's template, if applicable.
Use high-contrast colors so the audience can distinguish what is on the slides. Consider printing costs when deciding between dark on light and light on dark. For projection use a sans serif (Arial or Helvetica) font in a legible size no less than 24 picas. Make headings larger than the text and use bold and/or italics for emphasis. Provide your contact information for follow-up.
Limit the number of slides to no more than one per minute. Limit the text to eight words per line and eight lines per slide. Limit the use of transitions and animations.
Slide content augments rather than narrates the presentation. Select visuals such as graphs, diagrams, photos, and media clips to engage, clarify, and illustrate key points. Eliminate chart junk to increase readability.
Use bullet points sparingly and not more than three per slide. Number points when sharing a list or steps in a procedure.
Always include citations in presentations to academic audiences.
Provide a link to the online posting of your presentation as appropriate.

Electronic Communication

In business, email provides an efficient means of communication with others about circumscribed issues and allows immediate circulation of information and notice of events and updates. It is important to note that email does not replace face-to-face communication, although many organizations have relied heavily on email as a result of business disruptions due to the ongoing COVID-19 (coronavirus disease 2019) pandemic. Furthermore, email should not be used to discuss a complex topic requiring feedback.

The increased use of electronic communication brings challenges to traditional organizations. Email is common and borrows the latitude of speech in a format that seems like writing. This type of communication, with the casualness of speech but without the inflections or context, looks like written communication on the screen. Fragmented comments and speedy replies compound the potential for confusion, offense, and misunderstanding. Speed and spontaneity are the strengths of email but also its downfall. For some guidelines about when to use email, see Table 8.3.

Because emails are easily forwarded, never send something electronically not intended for public consumption. To maximize the utility of email, state the reason for the email in the subject line and borrow from standard letter writing conventions by being sure the message is correct, clear, and able to be understood. To maximize the use of email, follow some basic principles for sending and replying to emails (Table 8.4).

Electronic messaging is used extensively in most people's professional and personal lives. Text messaging, instant messaging, Facebook, Twitter, and Instagram are commonplace. The challenge facing organizations and people working in them is to determine what is

Table 8.3 Effective email communications

Recognize that emails are permanent and can be used in legal matters. Avoid revealing protected health information. Never send anything that should not be publicly shared. Maintain confidentiality and professionalism.
Never send anything that cannot be said directly to the recipient(s).
Copy others only as necessary and never as an exercise of authority, power, or manipulation.
Email works best as a means of circulating information, providing notice about events, giving someone a message, and communicating quickly and efficiently with a person about a circumscribed issue.
Never send an email when angry. Wait 24 hours and reconsider your options.
Avoid using email to discuss complex, controversial topics. These are best discussed face-to-face in a meeting.

本书版权归John Wiley & Sons Inc.所有

Table 8.4 Email tips

Email is used best for single-response or no-response communication with one or many.
Use the forward function sparingly.
Be especially careful when using the "reply to all" function.
Tips for Sending
Keep it short.
Try to limit the number of important questions or issues presented.
Include name and contact information in business emails.
Do not type messages in uppercase letters.
Tips for Replying
Reply promptly.
Reply to all the questions within the message, not just to the last question asked.
Think twice before hitting "Send." Avoid replying without thinking.

appropriate in specific work situations. Different understandings about what promotes better relationship building, essential to conducting business, are evident. Whereas young people beginning their professional careers may believe electronic communication suffices in all situations, senior managers tend to value more face-to-face meetings and may have trouble embracing new productivity-enhancing electronic tools. Generational differences in uptake and usage expectations while at work have received academic attention elsewhere (8, 9). The bottom line is to orient new staff members to your organization.

The goal of managers is to educate staff about the appropriate use of technology in their workplace. While texting might be fine in some instances, situations that require more extensive explanations or interactions are better dealt with face-to-face. Gestures and other nonverbal cues are absent in a text message. Text messaging can be misused and misinterpreted. Many of the rules (Table 8.5) for email apply to texting and may be incorporated into organizational policies.

Social networking sites such as Twitter, Facebook, LinkedIn, and SharePoint have established a significant workplace presence. Twitter is a hybrid broadcast/conversation communication platform. Facebook is more of an identity platform with communication and content distribution quickly adopted by employees to connect with friends, family, and colleagues. Work-related benefits center on creating and strengthening ties (8). LinkedIn, a business-related social networking site used for professional networking, focuses on professional information and is useful for maintaining external professional networks. In addition, many companies use Microsoft's SharePoint content management system to improve secure workplace communication by permitting rapid deployment of standardized information to multiple users across many sites that can be accessed on mobile devices.

Table 8.5 Texting in the workplace

Texting may be used to acknowledge compliments and accomplishments.
Always double-check texts before sending.
Never text apologies or criticisms. These are best handled face-to-face.
Never text personal messages on a company phone, as your employer has the right to check messages.
Never assume that others are familiar with text message shorthand.
Never text during a meeting, as this is very distracting and may be viewed as disrespectful.
Follow your organization's guidelines regarding texting at work.

Despite the benefits and growing popularity of social media, two primary concerns are evident: privacy and productivity. Significant privacy issues affect the organization as well as the individual. Some companies express concerns about the potential for inadvertent disclosures of proprietary information (8). Discussions of social networking in the workplace also revolve around the potential for loss of productivity. Some employers believe that providing access to social media sites encourages employees to engage in excessive personal activity during work time.

Companies rely on workplace communication to keep employees informed and to solicit input from staff. Social media is a valuable way to accomplish these tasks. Employee orientation to organizational guidelines and policies around expectations of social media use helps define and mitigate issues related to inappropriate use.

Visual Communication

Photographs, paintings, diagrams, cartoons, and caricatures are examples of pictures used as visual communication aids. Pictures may augment understanding of written explanations, particularly when one is addressing multicultural groups. The image being transmitted to the brain is drawn or formed more quickly than words are processed. Pictures support well-chosen words to help the receiver "see" the message. Videos, charts, posters, models, and digital pictures can equally convey powerful messages.

Visual communication is especially valuable in presenting a process or explaining how to do something. This can be used in training employees as well as in educating patients. For example, showing a video about performing venipuncture is much more informative than solely providing written instructions. Verbal instructions accompanied by pictures can be very helpful when teaching individuals how to perform a new complex or intricate procedure.

Body Language and Other Nonverbal Communication

Body language and other nonverbal cues reveal much about people's attitudes and feelings (4). Body language, or kinesics, describes human interaction excluding the use of

本书版权归John Wiley & Sons Inc.所有

written and spoken words. Historical studies indicate that more than half of all verbal messages sent include nonverbal components (10). Nonverbal communications researchers claim that as much as 90% of the meaning transmitted between two people in face-to-face communications occurs via nonverbal channels (11).

Nonverbal cues include posture, gestures, facial expressions, eye contact, and proxemics. For example, leaning toward the person speaking conveys attention and interest. In contrast, moving away while talking to a coworker sends the message that the meeting is over. Movement made with the eyes, mouth, or forehead conveys a great deal. A scowl usually signifies displeasure. A stern look can mean disapproval, while a smile means approval. The use of eye contact varies among cultures. In some, eye contact is understood as a sign of trustworthiness and credibility, and in others, disrespect.

Microexpressions are involuntary, subconscious facial expression flashes depicting raw emotion. Unlike regular facial expressions, microexpression reactions cannot be concealed. Microexpressions typically express disgust, anger, fear, sadness, happiness, surprise, and contempt. Learning to correctly interpret microexpressions can be helpful; however, jumping too quickly to conclusions can create misunderstanding (12).

Barriers to Effective Communication

Many times, well-planned and well-executed messages miss their mark because of barriers. The speaker and the listener each can create barriers to effective communication. A barrier in this context means any behavior that hinders the flow of meaningful, nonjudgmental communication. Barriers may be physical, nonverbal, verbal, and psychological. Upon becoming aware of a barrier, a manager should focus on controlling or removing it.

Physical Barriers

Physical barriers are structural or natural barriers in the organizational environment that can be detected and easily removed. Examples include reducing background noise, moving out of a busy area, removing furniture, adjusting the physical distance between participants, and providing participants with communications technologies such as a headset, phone, and software to overcome differences in space and time.

Nonverbal Barriers

There are several nonverbal behaviors impeding communication: inappropriate eye contact; unfavorable facial expressions, such as frowning, smirking, scowling, and blank looks; poor posture, such as slouching; and excessive fidgeting and squirming. Speakers and listeners can remain distant from each other by facing away from or turning their backs to each other or by demonstrating a lack of interest or a preoccupation with something else. These behaviors should be avoided (13).

Verbal Barriers

Verbal modes of delivery causing barriers to communication may be less detectable or correctable. However, once a speaker realizes that a problem exists, steps can be taken to correct it. Speakers assume that their language is understood by the audience and that the words used are familiar. Despite speaking the same language, an uninviting tone of voice, choosing words that are condescending, patronizing, or harsh, and using sarcasm inhibit effective communication. Speaking in a monotone or too quickly also impedes reaching a shared understanding of what has been said (14).

Psychological Barriers

Psychological barriers may develop in some environments. They may consist of preconceived expectations, self-centeredness, lack of self-esteem, and assumptions on the part of either the speaker or the audience members. Power and status perceptions or a defensive attitude may also cause psychological barriers (14). Though psychological barriers are more difficult to overcome, managers need to be aware that these types of barriers may be preventing optimal communication.

The Importance of Listening

Listening may be the manager's most important communication skill (15). Often overlooked, listening skills include the processes of receiving a message from a speaker, making sense of the message, and responding in ways that show that the receiver understands what the speaker means (16). Listening well increases job effectiveness. Ensuing dialogue ensures that parties reach a shared meaning through effective communication (5). Effective listening can help to remove verbal and nonverbal barriers.

Effective Listening

Conducting a positive exchange of information with employees is sometimes considered the most difficult aspect of communication and cannot occur without effective listening (5). Good communication encourages creative interaction between employees. When managers listen to employees and show understanding, employees believe they are valued as partners. Listening to employees leads to increased trust and credibility and an increased willingness to cooperate. In organizations, this generally means a reduction in turnover and a greater commitment to the organization's goals. Poor listening contributes to low employee morale and increased turnover because

本书版权归John Wiley & Sons Inc.所有

employees do not feel that their managers listen to their needs, suggestions, or complaints. Ineffective listening frequently causes misunderstandings, mistakes, jobs done incorrectly, unhappy customers, increased costs, and reduced profits. Listening more effectively enhances the transfer of information, improves teamwork, builds morale, reduces errors, and leads to higher productivity (15).

Ineffective Listening

There are five main reasons why managers do not listen effectively.

1. Listening is hard work. Listening requires concentrating on the other person rather than on oneself.
2. Listening competes for our attention with phones, computers, television, and more. People, as active information consumers, teach themselves to screen out information deemed irrelevant or unimportant.
3. Listening means not interrupting the speaker. Managers often interrupt and do not take the time required to hear people out.
4. Listening involves a gap created by the difference between speech speed and thought speed. The average person speaks at about 135 to 175 words a minute and can listen to 400 to 500 words a minute. The difference between the speaking speed and the speaking speed is time spent jumping to conclusions, daydreaming, planning a reply, or mentally arguing with the speaker.
5. Listening is a learned skill, and many have not been taught how to listen. People do more listening than speaking, reading, and writing, yet they receive no formal education in listening. Many assume they are good listeners; however, few are. Managers' listening skills can be improved upon by understanding the stages of listening and the types of listeners and by working toward improving listening skills (15).

Stages of Listening

Listening occurs in three stages: receiving, processing, and responding. Receiving consists of taking in the speaker's message by hearing and seeing. When people are speaking face-to-face, the eyes read the nonverbal cues that play a part in how the speaker expresses the message. After the receiver takes in the message, internal processing begins. Processing involves analyzing, evaluating, and synthesizing the message. In the third stage, responding, the speaker sees and hears what the receiver does. The receiver verbally and nonverbally acknowledges that the message has been received, or heard, and understood (13).

Types of Listening

People listen at one of four levels of attentiveness: nonlistener, marginal listener, evaluative listener, and active listener (15). Depending on the circumstances, listeners may fall into overlapping categories or move from one category to another. The potential for understanding, trust, and effective communication is highest when active listening is used consistently (16).

Nonlistener. The nonlistener does not hear anything the speaker says. The nonlistener is characterized by a blank stare and nervous mannerisms and gestures. Often, this type of listener pretends to pay attention while thinking about other, unrelated matters. Nonlisteners want to do most or all the talking, constantly interrupt, and always have the last word. They are perceived as insensitive and nonunderstanding (15).

Marginal listener. The marginal listener hears the sounds and words but not the meaning and intent. Marginal listeners are described as superficial listeners, are easily distracted, and prefer to evade difficult or technical presentations and discussions. Marginal listening is hazardous because there is enormous room for misunderstanding, since the listener is only superficially concentrating. In the workplace, this type of listener is often a source of low morale, misunderstandings, errors, and problems (15).

Evaluative listener. The evaluative listener actively tries to hear what the speaker is saying but does not try to understand the speaker's intent. Evaluative listeners are described as logical listeners who are more concerned about content than feelings. They remain emotionally detached from the conversation and evaluate a message based strictly on the words delivered, totally ignoring that part of the message conveyed by the speaker's tone, body language, and facial expressions (15).

Active listener. The active listener is the most comprehensive and powerful level of listener. Active listening is also referred to as responsive listening or reflective listening. It requires the deepest level of concentration, attention, and processing effort. The active listener focuses on understanding the speaker's point of view rather than constantly judging the speaker's message. Attention is concentrated on the thought and feeling of the other person as well as what the speaker is saying. Active listeners capture the speaker's whole message, i.e., the facts and the feelings. Active listening requires that the listener send verbal and nonverbal feedback to the speaker indicating that what is being said is being absorbed. Verbal feedback to confirm understanding of a speaker's message, given without being judgmental, makes active listening the most effective form of listening (13, 15).

Effective communication results when the speaker and the receiver are active listeners.

本书版权归John Wiley & Sons Inc.所有

Elements of Effective Face-to-Face Communication

Effective communication begins with developing an active-listening attitude. To develop this attitude, the listener must understand that active listening is as powerful as speech and saves time. Those who listen actively experience fewer mistakes, fewer misunderstandings, fewer dissatisfied customers, and fewer false starts. Managers must realize that listening is important and worthwhile no matter who is speaking. Organizations that promote active listening have fewer communication glitches, increased productivity, and increased morale.

Skills for Effective Face-to-Face Communication

Active listening is composed of six actions: (i) concentrate, (ii) acknowledge, (iii) research, (iv) exercise emotional control, (v) sense the nonverbal message, and (vi) structure (15).

1. *Concentrate*. Focus attention only on the speaker and diminish background noise to aid in receiving the message clearly. Eliminate distractions and physical barriers to create the best possible conditions to allow for a comfortable conversation.
2. *Acknowledge*. Acknowledge the speaker. Demonstrate interest and attention that encourages and helps the speaker to send a clearer message. This can be done by making eye contact and/or asking timely clarification questions. This gives positive feedback and helps the speaker know how the message is received. Wait several seconds before replying to indicate that the message was received and evaluated before the response was formulated.
3. *Research*. Ask questions about the speaker's interests and objectives to help understand the message, and respond to the speaker in a way that demonstrates interest, understanding, and dialogue.
4. *Exercise emotional control*. Wait until the entire message is received before reacting to the message. Deal with highly charged messages in a thoughtful manner regardless of how provocative the message may be. Concentrate on understanding the message before reacting.
5. *Sense the nonverbal message*. Pay attention to what the speaker is trying to say, which includes body language and gestures as well as the words being spoken.
6. *Structure*. Structure and organize the information as it is received, as this improves retention and understanding of the material.

Organizational Climate

In addition to becoming a more active listener, a manager must create and sustain a climate in which effective communication is supported. A manager who is not an effective communicator unknowingly promotes a workplace culture where effective communication is neither valued nor properly managed. This type of manager is unlikely to provide a feedback mechanism or hear about problems. The staff does not communicate their concerns about communication because management is perceived as unreceptive (17).

An effective organizational climate involves trust, openness, reinforcement of good communication practices, and shared responsibility for effective communication. It is up to the manager to be sure that they and their staff have the skills and knowledge necessary to communicate effectively. Effective communication requires attention and develops because of an intentional effort from both parties. Once the commitment has been made to improve communication, the manager must play a critical role in fostering and nurturing a climate that is characterized by open communication. The manager must bring communication to the forefront of the organization. This can be done by participating in formal training, providing training for others in the organization, actively soliciting feedback within the organization, defining how communication should occur, and making clear what information will be available and when, how, and where information will be communicated. A communication strategy should support, encourage, and reinforce the mission and culture of the organization (5).

When speaking to a group in a formal setting, a manager must speak assertively and should be an expert on the topic being presented. Managers need to prepare, be well versed on the subject beforehand, and anticipate questions that are likely to be asked. The message must contain the five Ws and an H—who, what, where, when, why, and how (18). On a personal level, the manager must be approachable and available. Effective communication during meetings involves more than the efficient flow of information (Table 8.6). In one-on-one conversations or in small groups, the manager can win the attention and confidence of the others by asking for their views on

Table 8.6 Effective communication during meetings

Listen to others' opinions and value them.
Compliment the work, help, or support of coworkers.
Ensure that there are no surprises. Do not bring something to a meeting that could embarrass or anger another person. Avoid criticizing someone at a meeting.
Avoid confrontation and ill words at a meeting. Nobody wins.
Do not dominate a meeting.
Be clear and open. Avoid cryptic statements.
Use clear, simple, and appropriate language to address the audience.
Include the six W/H (who, what, when, where, why, and how) points.
Do not misrepresent or overdramatize what was said at a meeting to someone who was not present.

本书版权归John Wiley & Sons Inc.所有

the subject. This can be done by asking "who," "what," "where," "when," "why," and "how" questions. This communicates the manager's interest in the topic of the conversation and the other person(s) (19).

Using Body Language

Body language refers to everything done with the body to express a message. The better the manager can transmit messages so that they are received by others as they were intended, the more effective the manager. Managers need to be acutely aware of the nonverbal messages they are always sending. A sensitive, perceptive manager uses the nonverbal feedback they receive from the other person to adapt the organization and style of their message. The ability to project favorable body postures and to read the body language of others is an asset to everyone working in groups (11).

Maintain steady eye contact. Look at the person when talking to them without staring or glaring. Sit up and face the receiver. It is helpful to lean forward occasionally as well. Show positivity through facial expression by having facial expressions match your voice inflections. Body language pitfalls to avoid include slouching, invading space, hovering over the listener, looking blank or stern, displaying threatening gestures (finger pointing or pounding a fist on the table), folding arms, and having distracting habits (e.g., picking, scratching, swirling, pulling on jewelry, or rattling change).

Body language is an essential part of interpersonal communication. Once managers are aware of the importance of body language, they can adapt theirs to different audiences and situations.

Using Positive Language

How a manager uses language is an exceedingly powerful tool. Whether communication is in oral or written form, how the message is expressed affects whether the message is received positively or negatively. Negative language creates a negative environment and increased confrontation. A manager who uses negative language frequently criticizes ideas without offering suggestions or alternatives. Negative language usually tells a person that what he or she has done is wrong, without stressing the positive things that can be done to remedy the problem. Positive language stresses positive actions and positive consequences and suggests alternatives and choices while sounding helpful and encouraging rather than bureaucratic. If managers realize that they use negative language rather than positive language, they can start improving their communication strategy by incorporating positive language in written material. Once this has been accomplished, it will be much easier to change spoken language to present a more positive tone. This is most helpful in the workplace. Negative language conveys a poor image to coworkers and customers. Positive language projects a helpful, positive image that improves the organizational climate (17).

Leadership Essentials for Improving Communication

An effective communicator is a catalyst in the workplace. A catalyst in a laboratory setting is defined as a substance that heightens or accelerates a reaction. In the workplace, a catalyst is someone who sparks action in others. Managers must choose to consistently behave in ways that energize and mobilize others. There are several attributes that are essential to a successful catalyst's behavior. The first is trust, which is an essential ingredient of success. The second is respect. People deserve respect, and there is value in diversity. The third is support. A key role of the leader is to support others. By exhibiting these characteristics, catalyst leaders practice what they preach, make a long-lasting difference in the lives of the people who look to them for guidance and support, and influence people who can make a difference. Successful catalysts are effective communicators. An integral part of this communication includes understanding the interaction process as well as the preferred communication styles of others.

The Interaction Process

When people interact, they generally have practical and personal needs. Achieving a productive outcome can satisfy practical needs. Personal needs include feeling supported, valued, understood, and integral to the organization.

The interaction process consists of five guidelines that equip the manager with the skills needed to be successful. The five interaction guidelines are to open, clarify, develop, agree, and close. When opening a discussion, state the purpose, the importance of the purpose, and the benefits of accomplishing it. Clarify the discussion by presenting facts and figures you have collected and then using them to explore issues and concerns. Develop the discussion by involving the person or group by seeking their ideas. Agree on a course of action by specifying what will be done, who will do it, and a date when it will be done; also, agree on a tracking process. Close the discussion by confirming that everyone is clear on the subsequent steps and committed to following through with these steps. These guidelines satisfy practical needs by ultimately ensuring that the discussion achieves its purpose. The guidelines for clarifying, developing, and agreeing can be used multiple times in a discussion. To keep the discussion moving and on target, the manager must remember to check for understanding and make procedural suggestions when appropriate. Using this process provides the framework for the discussion and ensures that the discussion achieves a productive outcome.

本书版权归John Wiley & Sons Inc.所有

The interaction process equips a manager with the skills needed to be successful in any type of discussion or communication.

The interaction guidelines should be used in tandem with five key principles to meet personal needs, build trust, and build stronger working relationships among staff. The principles are to maintain or enhance self-esteem; to listen and respond with empathy; to share thoughts, feelings, and rationale; to ask for help and encourage involvement; and to provide support without removing responsibility. When the manager communicates using these key principles, the supportive manager encourages trust. By consistently using the interaction skills and key principles during interpersonal interactions the manager can achieve critical business objectives while enhancing working relationships, which in turn enhances communication.

Meaningful, supportive feedback is also essential to achieving success within an organization. Effective feedback should be timely, balanced, and specific. Timely positive feedback strongly reinforces positive actions and results. Timely developmental feedback provides suggestions soon enough for people to adjust and enhance their performance. Effective feedback balances suggestions for improvement with reinforcement. Specific feedback provides a distinct picture of present performance and clear guidance on actions that will increase the likelihood of success in the future. Staff should be told what they accomplished (or did not accomplish), how they achieved results, and why their actions were effective. This type of feedback is effective because it provides a complete picture of expected performance and enhances communication.

Adapting Communication Styles

One way to enhance effective communication is to modify one's communication style to match the preferred style of the individual with whom one is communicating. Individuals can be categorized in one of four ways: active doer, methodical plodder, people person, and thinker. Active doers like a minimal amount of discussion and a quick resolution. They prefer bulleted information items with an outline of key points. Active doers want things to happen "yesterday." Methodical plodders thrive on extensive facts and data with multiple channels of input. They prefer to mull the situation over extensively before making a decision or a commitment. People persons prefer a personable approach. They do not want to be inundated with facts and data and are more interested in how issues or problems relate to people. Thinkers visualize the finished product but are not interested in the details. They have no idea how to translate needs into a finished plan and become bored quickly with facts and figures. Effective communicators understand these categories, know their audience, and adapt their communication methods to match the individual (Table 8.7).

Table 8.7 Adapting communication to specific audience styles

Listener type	Nonproductive communication	Productive communication
Active doer	Long explanations	Bullet points
Methodical plodder	Bullet points	Long explanations
People person	Memos, emails	Personalized meeting
Thinker	Details	Big picture

SUMMARY

Effective communication is critical to any organization's success. Effective communication is a two-way street that requires talking and listening skills. Better managers realize that they do not have a monopoly on experience and knowledge. They do much more listening than talking because they know that talented individuals can be found in every possible job in an organization, from the very bottom rung of the corporate ladder all the way to the top. By listening, managers often hear good ideas. They must evaluate the situation and decide whether they are best served by taking control and directing the conversation or by listening, asking questions, and collecting ideas (1).

To be effective communicators, managers must acquire a variety of skills and learn when to use the appropriate ones. One of the most important skills is active listening. Better managers learn and use active-listening techniques. This sets the tone and contributes to a positive communication climate (19). Better managers realize the importance of identifying and handling communications barriers. Better managers handle these barriers by preparing, planning, and organizing the environment as well as taking the time for an exchange of communication. Employees are more receptive when the manager acts in a supportive and positive manner. Communication between managers and employees supports performance and work quality (14). Every communication is an opportunity to enhance or destroy relationships (Table 8.8).

In every organization, communication from the manager must be considered credible. Credibility means that the staff finds the manager believable, trustworthy, and deserving of respect. A manager earns credibility by taking positive

Table 8.8 Communication tips to build strong working relationships

Be positive and upbeat.
Engage and smile at others.
Be up-front—no hidden agendas.
Give criticism politely and always privately.
Remember things that are important to others.
Respect others and their opinions.
Do not say something behind someone's back that cannot be justified or said to them directly.
Listen actively.

本书版权归John Wiley & Sons Inc.所有

actions after interactions with staff. These actions must match positive words and good intentions. Credibility can be earned by following through, demonstrating expertise, remaining calm under pressure, taking positive approaches to problems, showing sincerity, and listening before acting.

Managers enhance communication by being a catalyst to others in the organization. Communication improves when managers use interaction processes that meet the practical and personal needs of staff. Better managers adapt their communication style to match the individual with whom they are communicating.

Successful managers are effective communicators who achieve and maintain credibility with those above them, laterally, and with those below them, thereby contributing to a positive workplace culture. Effective communication benefits the entire organization, since communication helps in accomplishing tasks and solving problems. Effective communication requires planning, setting the climate and tone, removing barriers, speaking and writing clearly, listening actively, and presenting information in an articulate manner.

KEY POINTS

- Effective communication is essential to all aspects of the work environment. The ability to communicate is essential to leadership and vital to every organization.
- While formal channels are the primary means of official communication, the grapevine exists in every organization. Management can often use the information from the grapevine as well as providing the grapevine with facts.
- Electronic communication is in the workplace to stay. This includes emails, texts, and social media. Use electronic communication judiciously and beware of pitfalls. Follow organizational guidelines for usage.
- Evaluate the situation, the audience, and the content of the message to determine the most effective type of communication.
- Identify communication barriers. Work toward eliminating or controlling communication barriers.
- Become an active listener. Learn active-listening techniques and use them consistently.
- Foster an organizational climate that supports effective communication.
- Recognize nonverbal messages, both those you are projecting and those you are receiving.
- Utilize positive language when possible.
- Practice the interaction process and use it to meet the practical and personal needs of the staff.
- Give positive feedback.
- Adapt your communication style to match the individual with whom you are communicating.

GLOSSARY

Active listener One who listens to the whole message, including facts and feelings.

Communication The exchange of thoughts, messages, or information by multiple mechanisms such as speech, signals, or writing.

Communication barriers Any behavior or physical obstruction that hinders or restricts the flow of meaningful communication.

Evaluative listener A listener who hears the words but makes no attempt to understand the feelings of the speaker.

Formal channels of communication Communication networks designed to follow the structure (lines of authority) of the organization.

Informal channels of communication Informal routes that people use to spread information to one another.

Marginal listener One who hears the words but does not comprehend the intent.

Negative language Words or phrases used to express and communicate thoughts and feelings by using excessive criticism and confrontation.

Nonlistener A person who does not hear anything that is said.

Organizational culture Social and artistic expression, characteristic of a community or population, that pertains to behavior patterns, arts, beliefs, institutions, and all other products of human work and thought.

Positive language Words or phrases used to express and communicate thoughts and feelings by using positive actions and consequences.

ACKNOWLEDGMENT

Diane C. Turnbull, the author of the previous second edition version of this chapter, is gratefully acknowledged for her contributions to this edition.

REFERENCES

1. **McGinty SM**. 2001. Putting language to work, p 87. *In* McGinty SM (ed), *Power Talk: Using Language to Build Authority and Influence*. Warner Books, Inc, New York, NY.

2. **Bacal R**. 2012. Improving communication—tips for managers. http://work911.com/conflict/carticles/impcom.htm. Accessed 1 August 2021.

3. **Alessandra T, Hunsaker P**. 1993. *Communicating at Work*, p 14–16. Simon & Schuster, Inc, New York, NY.

4. **Brounstein M.** 2001. *Communicating Effectively for Dummies*, p 323–327. Hungry Minds, Inc, New York, NY.

5. **Adams B.** 2001. *The Everything Leadership Book*, p 16–25. Adams Media Corporation, Avon, MA.

6. **Tufte ER**. 2006. *The Cognitive Style of PowerPoint: Pitching Out Corrupts Within*, 2nd ed. Graphics Press LLC, Cheshire, CT.

本书版权归John Wiley & Sons Inc.所有

7. **Paradi D**. 2012. Ten secrets for using PowerPoint effectively. https://www.thinkoutsidetheslide.com/ten-secrets-for-using-powerpoint-effectively/. Accessed 1 August 2021.

8. **Skeels MM**, **Grudin J**. 2009. When social networks cross boundaries: a case study of workplace use of Facebook and LinkedIn, p 95–104. *In* Proceedings of the ACM 2009 International Conference on Supporting Group Work, Sanibel Island, 10–13 May 2009. https://dl.acm.org/doi/10.1145/1531674.1531689. Accessed 9 August 2021.

9. **Neves BB**, **Amaro F**, **Fonseca JRS**. 2013. Coming of (old) age in the digital age: ICT usage and non-usage among older adults. *Sociol Res Online* **18**:22–35.

10. **Martin BG**. 1982. Communications, p 133–158. *In* Karni KR, Viskochil KR, Amos PA (ed), *Clinical Laboratory Management*. Little, Brown and Company, Boston, MA.

11. **Alessandra T**, **Hunsaker P**. 1993. *Communicating at Work*, p 120–122. Simon & Schuster, Inc, New York, NY.

12. **Ekman P.** 1997. Should we call it expression or communication? *Innovation (Abingdon)* **10**:333–344.

13. **Brounstein M.** 2001. *Communicating Effectively for Dummies*, p 51–56. Hungry Minds, Inc, New York, NY.

14. **Wallace MA**, **Klosinski DD**. 1998. *Clinical Laboratory Science Education and Management*, p 238–247. WB Saunders Company, Philadelphia, PA.

15. **Alessandra T**, **Hunsaker P**. 1993. *Communicating at Work*, p 54–68. Simon & Schuster, Inc, New York, NY.

16. **Brounstein M.** 2001. *Communicating Effectively for Dummies*, p 27–38. Hungry Minds, Inc, New York, NY.

17. **Bacal R**. 2012. Using positive language. http://work911.com/articles/poslan.htm. Accessed 1 August 2021.

18. **Lemery LD**. 2002. Communications at the 95% confidence level: the impossible dream? *Clin Leadersh Manag Rev* **16**:129, 127–128.

19. **Blair GM**. 1992. Conversation as communication. *Engineering Management J* **2**(6): 265–270.

本书版权归John Wiley & Sons Inc.所有

9

Effective Meetings

Mark G. Hanly

Introduction
Things To Do before a Meeting
Determine If There Is a Need for a Meeting • Determine What Type of Meeting Is Needed • Develop the Agenda • Use of the Consent Agenda • Determine Whom To Invite to the Meeting • Determine the Venue of the Meeting • Determine the Technology/Equipment Required for the Success of the Meeting
Things To Do during a Meeting
Things To Do after a Meeting
Calculating the Cost of a Meeting
Recurrent Meetings
How To Be an Effective Participant in a Meeting
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES

OBJECTIVES

To help the reader determine whether to have a meeting
To evaluate different methods of disseminating information
To outline different meeting types
To explain how to set up and run an effective meeting
To provide pointers on how to be an effective meeting participant
To outline how to troubleshoot meeting problems
To help managers calculate the cost of a meeting

People who enjoy meetings should not be in charge of anything.

Thomas Sowell

If you are involved in any form of laboratory management, you will undoubtedly have had that dreadful sensation, after leaving a long, rambling, poorly organized meeting, that you have wasted an entire morning while work that really needs to be done is piling up on your desk. Meetings have become the bane of modern clinical laboratory management; they are extremely expensive in terms of personal and employee time and can cost significant amounts of money for disposables, paper, and copying charges as well as refreshments. Poorly organized, ineffective meetings are not only an incredible waste of resources, which can damage the bottom line of any organization, but they can also be significantly damaging to staff morale (1). In the corporate world, meeting costs have been estimated to result in billions of dollars of wasted productivity annually (2).

Despite these observations, an effective meeting is an essential tool in the efficient management of a laboratory. However, all meetings must be planned and managed, or they will fill those involved with a dread that stifles any utility the meeting might have had (3, 4). Directing an effective meeting or being an effective participant in a meeting is an important way to cultivate in your staff the goal of working smarter and not harder.

Below is a synopsis of the steps required to ensure that any meeting you convene will be as effective as possible. The steps can be placed into three general categories, although there is some crossover: (i) things to do before the meeting, (ii) things to do during the meeting, and (iii) things to do after the meeting.

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch9.

本书版权归John Wiley & Sons Inc.所有

Things To Do before a Meeting

Determine If There Is a Need for a Meeting

In essence, there are at least six reasons to hold a meeting:

- To comply with regulatory requirements
- To make a decision that requires the input of several people
- To coordinate action on an issue
- To discuss a specific problem with the goal of achieving a solution
- To convey information to a group of people
- To motivate a group or team

Each of these reasons will require a meeting with a slightly different structure, but the key components of holding an effective meeting remain true no matter what the setting.

Before a meeting is called, it is necessary to evaluate if there is a better way of communicating with the group (5). If the issue is a simple, straightforward, easily understood transfer of information, it is quite acceptable to inform staff of a decision with a clear, well-thought-out memorandum. This may be issued in written form, sent via email, or, in some modern laboratory information systems, programmed to appear on the sign-in screen at the time of employee log-on. However, if it is decided that a meeting is needed, planning is essential for success, and attendance expectations must be clearly set from the beginning.

Determine What Type of Meeting Is Needed

An important factor in the strategy for arranging a successful meeting is for the convener to have a clear idea of why the meeting is being called. The convener must have defined goals in mind and must ensure that sufficient planning has been undertaken to secure those goals.

In the past, a "meeting" essentially meant a face-to-face encounter with all participants in a single room. While this is still a common form of meeting, public health considerations, such as the coronavirus disease 2019 (COVID-19) epidemic (6), the growing size of healthcare campuses, consolidation of organizations (7), and the increased complexity of practices, institutions, and laboratory companies, as well as the development of new technology, have caused other forms of meeting formats to become more common, and these may be more appropriate and cost-effective than the traditional single-venue meeting.

Meeting options include the following:

Face-to-face meeting. This is the most traditional way of holding a meeting but requires booking of an appropriate venue, coordination with other departments such as information technology to ensure that equipment is ready, and prolonged time away from one's work area. In a large hospital complex, walking from one end of the campus to the other may easily add up to 30 minutes on either end of the meeting. This means that even a scheduled 60-minute face-to-face meeting will require 2 hours of the workday. The great advantage of a face-to-face meeting is that this setting facilitates personal contact, which allows for the building of networks, imparting organizational ethos and the development of working friendships, which are important in navigating the complexities of large healthcare facilities. This environment also permits attentive participants to read nonverbal cues and body language from other participants. The question of whether to provide refreshments is often asked. It is my opinion that all refreshments provided at meetings are a distraction to the purpose of a meeting and their provision should be strongly discouraged.

Telephone conference call/teleconference/voice-only online conference. Voice-only conferences are best utilized for small numbers of participants and urgently called meetings with limited agendas, but with planning, they may be utilized for most meetings. They have as a great advantage the reduction in the need for travel or time away from the office, but the disadvantages are the generally limited number of participants and the inability to read nonverbal cues—that is, the nuances derived from facial expressions and body language may be missed. In addition, the temptation is always there for participants to multitask or be distracted by local issues. The participants need to be familiar with the equipment used, and as with any setting, easily accessible technical support is essential. Most hard-wired office telephones now have buttons to permit conference calls, and if the in-house information technology (IT) team does not have the facilities or skill set, there are several companies that can organize these calls through toll-free numbers or over the web (for example, https://www.freeconference.com and https://www.goto.com).

Videoconference. Videoconferences are increasingly being utilized, particularly since the advent of the COVID-19 pandemic and in the setting of large organizations spread over several locations. If adequate equipment and technical skills are available, this type of conference can be arranged by internal IT teams. However, several companies now offer simple and easy-to-use online videoconferencing services that greatly facilitate the introduction of this type of technology (e.g., www.webex.com, www.zoom.us, http://meet.google.com, www.skype.com). As with conference calls, this type of meeting has the great advantage of not requiring travel, but a degree of participant familiarity with the technology is needed, and appropriate technology and IT support must be available to allow participants to actively and usefully engage in the proceedings.

本书版权归John Wiley & Sons Inc.所有

Although managing large numbers of participants in a video conference can present unique challenges, such as the temptation for participants to multitask and disengage from the meeting, if clearly defined rules of participation are employed, they can be very effective. Videoconferencing does allow for improved but not complete access to the nonverbal cues of the meeting participants. This technology also allows for instant distribution and demonstration of presentations such as PowerPoint images. It is important to understand that the utilization of this technology does not negate the need for proper planning; indeed, it probably makes detailed planning even more essential. Each type of meeting can have varying implications for participants, but it is important for virtual meeting conveners to actively ensure that all opinions are engaged and avoid gender bias (8, 9). There is also evidence that there may be unique psychological implications arising from the perceived increased visual intensity of videoconferencing, for which the term "teleconferencing fatigue" has been coined (10, 11).

Pros and cons of each of these modalities are provided in Table 9.1.

Table 9.1 Meeting types

Meeting Type	Pros	Cons
Face-to-face	Traditional Easy to manage Limited technology needed Large numbers of participants can be accommodated without overwhelming confusion Nonverbal cues available	Venue needed Staff members may be away from office Increased cost due to travel time
Telephone conference	No travel time needed Side discussions less common Limited technology needed	Technological skill required of participants Nonverbal cues cannot be read as easily Networking hindered Distractions may be increased by participants' temptation to multitask Possible limitation of the number of active participants
Videoconference	No travel time needed Better evaluation of nonverbal cues Permits visual sharing of presentations	Technological skill required of participants Technical equipment needed Possible limitation of the number of active participants

Develop the Agenda

The next step in conducting an effective meeting is developing an appropriate, well-thought-out agenda. While in the past it was routine to develop an agenda along the lines of Robert's rules of order, it is now more common to dispense with this style for a more efficient and user-friendly format. Consideration should be given to including an "Action Plan" column in all agendas. This is a feature designed to drive the meeting toward setting goals and implementing decisions that have been made.

Planning the agenda should begin early. The meeting convener should send out a request for agenda items as soon as planning for a meeting begins. If the meeting consists of a small defined group, it may be worthwhile to develop a folder for each participant that includes the agenda, minutes from the last meeting, supporting documents, etc. This provides the attendees with all the information required to participate fully in the events. These folders can be returned or collected at the end of the meeting and refreshed for use and distribution at the next scheduled meeting. In any other setting, distribution of information electronically well before the meeting is advised to permit attendees to familiarize themselves with the agenda items and adequately prepare for the meeting.

While agendas will vary to some extent depending on the nature of the meeting and the issues to be discussed, a useful agenda should be designed to provide the following information.

- Meeting title
- Meeting venue with instructions, if necessary, on how to get to the meeting or detailed instructions on how to call in to a conference call or sign in to a videoconference. It is essential to provide details as to how a participant can access IT support if technological barriers arise.
- Scheduled date and time of the meeting
- Contact person in charge of developing the meeting
- List of people/departments invited to the meeting
- Order and type of presentations
- Time allotted for each presentation
- Information that must be assimilated, evaluated, or brought to the meeting
- Clear indications of what agenda items are informational, what items will require identifying a solution, and what items will require a vote.
- An action column for notes, decisions, and votes.

Do not overload the agenda. Meetings that extend over 60 minutes rarely produce useful results. Try not to waste valuable meeting time by a long recitation of routine reports or other standardized, uncontentious information. This can be curtailed by considering the use of a consent agenda. Figure 9.1 provides a sample agenda.

本书版权归John Wiley & Sons Inc.所有

[Organization/Department Name]

Meeting Agenda

Meeting Date:

Meeting Time:

Meeting Venue:

Sign-on details: (If needed)

Type of Meeting: In person/Voice Teleconference/Video Conference

Meeting Chair/Convenor: Name / Email / Contact telephone number

Meeting Facilitator: Name / Email / Contact telephone number

Meeting Technology Support: Name / Email / Contact telephone number / Help Desk telephone number

Invitees/Participants:

ITEM	PRESENTER	TIME ALLOCATED	FOR REVIEW	ACTION
Call to Order	Chair	1		None
Approval of Minutes	Chair	5	Pages 1-5	Vote
Consent Agenda	Chair	5	Pages 6-10	Vote
Open Items				
Item 1	Name of presenter	10	PowerPoint	
Item 2	Name of presenter	5	Page 11	
Committee Reports (may be included in consent agenda)				
	Name of presenter			
New Items				
Item 1				
Item 2				
Closing				
Summary				
Next meeting				
Adjournment				

Figure 9.1 Sample meeting agenda.

Use of the Consent Agenda

A consent agenda (also called consent calendar) is a bundle of items that is voted on, as a package, without discussion. It differentiates between routine matters not needing explanation and more complex issues requiring more detailed examination and decision making by the meeting participants. Consent agendas may therefore be used to maximize the effectiveness of some types of meetings by allowing participants to focus on the agenda items that matter most (12). The use of a consent agenda will require the convener to decide on the items that warrant full discussion. While experience will assist in determining those components of the agenda that will be placed in the consent agenda, attendees must have an opportunity, prior to or at the start of the meeting, or at least prior to voting, to request removal of items from the consent agenda so as to allow discussion. Items most commonly found on consent agendas include minutes from previous meetings, confirmation of decisions that have been discussed previously, and routine informational reports that need no discussion or action from members of the meeting. While it is a valuable tool and not difficult to use, a consent agenda requires discipline along with the following:

- Clear unambiguous distinction between the components of the consent agenda and the items within the agenda
- Distribution of the complete consent agenda material in advance of the meeting
- Requirement that all meeting participants read the materials in advance
- Willingness of the convener, if requested by a meeting participant, to remove an item from the consent agenda
- A unanimous vote by meeting participants in favor of accepting all components of the consent agenda

本书版权归John Wiley & Sons Inc.所有

Determine Whom To Invite to the Meeting

Determining who will be invited to attend the meeting will, of course, depend on the type of meeting. However, the following points are useful to remember when developing the list of participants.

- Invite only those stakeholders whose input is relevant to the meeting. Requiring people to attend meetings unrelated to their responsibilities is expensive in manpower hours, wastes their time, and can be demoralizing.
- It is my opinion that the ideal committee size is either three or five people who have been delegated sufficient authority to act on agreed-upon decisions.
- Ensure that representatives from appropriate departments are invited. Sometimes this requires extensive premeeting planning to identify who would be most suited to deal with agenda items.
- If someone is not usually invited to a particular meeting and the convener believes that this individual's attendance is necessary, it is important for the convener to call the participant and explain why his or her presence is important. This can be very insightful and may indeed change a decision as to who should appropriately be invited to the meeting.
- Confirm with the attendees that they know the information they will be required to bring or present. This can be done by an email and placing a note on the agenda at the time of its distribution.

Determine the Venue of the Meeting

The following points should be considered when deciding on a meeting venue.

- If a face-to-face meeting is to be held, choose a venue with sufficient room for the invited attendees.
- Ensure that the room has been booked in accordance with facility guidelines and that the facilitator or convener has obtained a confirmation of the booking.
- Choose a centrally located venue, if possible.
- For any recurrent meeting, try to book the same venue every time.
- Choose a venue with easy access, if possible. Unless necessary, avoid choosing venues in buildings with enhanced security or in obscure areas of the facility.
- Choose a venue with accessible parking if participant travel is expected.

Ensure that the room is suitably set up for any technology you intend to use in the meeting, such as a projected presentation or potential conference call participation by those staff who cannot make the meeting in person.

Determine the Technology/Equipment Required for the Success of the Meeting

Many face-to-face meetings include agenda items that will require the use of technology, such as video projection, or there may be a combination of technologies, including videoconferencing utilized as a component of a face-to-face meeting. Unless the convener can provide all of the required technology, it is essential that the responsible department for the facility, such as the IT team, be contacted to ensure that the appropriate connectivity and equipment are available, in place, and working at the time of the meeting. If the number of participants in a meeting is large, consider requesting appropriately placed microphones to ensure that all participants can be heard. Conveners should familiarize themselves with the technology they will be using.

Things To Do during a Meeting

Like an orchestra, a meeting brings together the individual players in an organization. Just as a conductor adapts to the type of music being played, it is essential for the meeting convener to adapt to the meeting type. Therefore, just as with an orchestra, it is important for a meeting to be controlled, or even in the most experienced groups disorder will soon prevail. The following are steps the convener should take to make controlling the meeting easier.

- Arrive or sign in early and make certain that the meeting (real or virtual) room is appropriately set up and that all the technology required is working. It is extremely disheartening to waste valuable time before or during a meeting dealing with nonfunctioning projectors, video links, or software.
- In virtual meetings, ensure that participants know how to indicate that they have a question to ask or a contribution to make.
- Where appropriate, take a roll call to ensure that all needed participants or departmental representatives are present.
- In taking control of the meeting, do not be rude but do be assertive.
- Speak audibly and definitively.
- Ensure that the meeting starts on time.
- Commence the meeting by bringing everyone to order.
- In virtual meetings, ensure that all participants are connected.
- Set the tone for the meeting by being enthusiastic and interested.
- Clearly state the reason for and goals of the meeting.

本书版权归John Wiley & Sons Inc.所有

- If components of the meeting are confidential, take an early opportunity to remind participants of this fact.
- If this is the first meeting of a particular group, introduce yourself and ask attendees to provide a brief introduction for themselves, including who they are representing. This is particularly useful in virtual meetings when there is risk of participant anonymity.
- If the meeting is an established group and a new person has been invited to the meeting, introduce the new attendee, and again allow everyone the opportunity to provide a brief introduction for themselves.
- If a consent agenda is to be utilized, complete its adoption as the first item in the proceedings.
- While ensuring that all components of the agenda are addressed, consider a dynamic approach to the agenda, particularly if there is a participant who is present only for a single agenda item. Allow that person to present his or her information early and then leave rather than sitting through the delivery of information that has no relevance for them.
- Pay attention to what is being said and keep the discussion on the relevant topics. Refocus the conversation when needed.
- Define guidelines as to the use of non-meeting-associated electronics. Stakeholders must be reminded about the need for muting cell phones, curtailing instant messaging unrelated to the meeting, and other sources of interruption.
- Be prepared to request clarification of any answer given by a participant if it is unclear. At times, particularly if you see that other participants are confused by the answer, it may be useful to confirm that they have understood the information.
- Interruptions can be very disruptive to meetings. Although this is difficult in the healthcare arena, discourage all interruptions and make it clear to your personal staff that you are in a meeting and should be contacted only in the event of an emergency. Showing this form of courtesy to the people you have brought to the meeting indicates the degree of importance you place on their time.
- Control meeting time.
- Questions will inevitably be part of every meeting. If some agenda item obviously requires more detailed discussion, consider the formation of a subcommittee, which can report back after studying the issue, complete the tasks, or delegate the issue for consideration.
- Make appropriate notes of proceedings to include in the minutes.
- Ensure that meetings within meetings do not arise. If a group within the meeting begins to discuss a topic separate from the agenda, indicate that you will provide them an opportunity to discuss the topic if needed at the end of the meeting.
- Ensure that when a decision has been made, it is clearly stated in the minutes, and make certain that the action has been clearly defined and that both the person responsible for the completion of the action and the time by which it must be completed are understood. In other words, define the action in terms of "What action; by whom; by when." Some new online meeting platforms have features which facilitate the contemporaneous development of minutes.
- As you approach the end of the meeting, spend a moment to recap the meeting's achievements. If necessary, a brief review of decisions and commitments made can be very useful.
- Ensure that the attendees leaving the meeting have understood what is required of them, and ensure that all questions have been answered.
- Spend a few moments discussing the next meeting in terms of date, venue, and agenda items.
- After the meeting, ensure that minutes, documents, and any material of a confidential nature have been collected and removed from the meeting venue.

Things To Do after a Meeting

As soon as it is feasible after the meeting, the convener and, if present, the person responsible for taking the minutes should meet and review all documents and notes prior to completing the official record of the meeting. Accurate, timely distributed minutes are important to document the decisions made at the meeting, and in addition, they can be key to ensuring that participants complete the tasks allotted to them. After the meeting, the minutes should be promptly prepared and distributed to all attendees. The minutes must clearly indicate the name of the meeting, the date on which the meeting occurred, the individuals present at the meeting, the decisions made, and the responsibilities assigned. While there is no necessity for the minutes to report verbatim what was said, meeting participants who presented should be identified in the minutes, as should participants who offered motions, seconded motions, and voted. If a vote was required and the vote was not unanimous, it is useful to identify who voted for and against a particular decision. If action is to be taken, the nature of the action, who is responsible for taking the action, and when the action will be completed must be clearly stated.

本书版权归John Wiley & Sons Inc.所有

Calculating the Cost of a Meeting

As mentioned above, meetings can be expensive. Although it can be difficult to determine the true cost of a meeting, the most expensive component is the salaried time of the participants. Several calculators are available online which facilitate the calculation of a meeting to an organization (https://hbr.org/resources/html/infographics/2015/11/meeting-cost-calculator/index.html).

Recurrent Meetings

While some meetings, particularly those required by accreditation agencies and medical staff bylaws and ongoing meetings to continue the direction of a busy laboratory, will have to be scheduled regularly, not all "meeting series" should be considered a commitment for life. Meetings designated for a particular activity, such as the introduction of a new piece of equipment or a new laboratory information system, should have a defined life span. Once the task allotted to the group has been completed, the meeting series should end. Indeed, it is often worthwhile with any regular scheduled meeting to periodically discuss with the participants whether the meeting still needs to be held or whether the meeting frequency needs to be changed. If a meeting regularly runs over the allotted time because too many items are on the agenda, it may be worthwhile to meet more frequently with a more manageable agenda.

How To Be an Effective Participant in a Meeting

Although much of the material above is most relevant for a person who is planning a meeting, skills are also required to be a useful meeting participant (5). Preparation prior to the meeting is as important for the participant as it is for the meeting convener. The following points will assist you in being an effective participant.

- Review the agenda before the meeting.
- Read the minutes from the previous meeting.
- Make sure that you understand any supporting documentation provided for discussion at an upcoming meeting.
- If the meeting includes consent agenda items, evaluate the items in the consent agenda so that you are in an informed position to agree to the agenda or request items be withdrawn for more detailed discussion.
- Make sure that any presentation you are to make is succinct and clear.
- If you are providing a presentation, ensure that the presentation is correctly loaded onto the flash drive you are using and that you are ready to access it efficiently.
- If you are bringing documentation for distribution, ensure that there are enough copies for all those who will be required to read and evaluate the document.
- If particular questions can be anticipated, make a brief note of what issues may need to be discussed or brought up for clarification at the upcoming meeting.
- Make clear to your staff that you are in a meeting and should not be disturbed except for an emergency.
- Consider placing your phone and pager in silent mode.
- Arrive or sign in on time.
- Wait your turn to talk. In most meetings the convener will indicate when you are to speak.
- Speak clearly.
- Listen attentively and participate actively.
- Keep the discussion and comments pertinent to the agenda items.
- Answer definitively.
- Monitor your nonverbal cues to ensure efficient, nonconfrontational completion of the meeting.
- Take notes, particularly with regard to tasks requested of you.
- Be attentive and not distracted by cell phones, etc.
- Do not interrupt others when it is their turn to speak.
- Do not initiate or participate in secondary conversations.
- Do not reopen decisions from prior meetings unless it is pertinent to ongoing business.

SUMMARY

Face-to-face meetings are not always required to share information. Technology has advanced to a point where in-person meetings are not always required or preferred. Unnecessary or poorly planned meetings can be wasteful of resources. However, if after consideration the decision has been made to hold a meeting, define the goal of the meeting, prepare for the meeting in detail, and control the meeting environment. Being an effective participant is also key to a meeting's success and will allow you to work smarter rather than harder. Specific recommendations for dealing with meeting problems are presented in Table 9.2.

本书版权归John Wiley & Sons Inc.所有

Table 9.2 Quick reference guide for troubleshooting meetings

Problem	Solution
Meeting seems to have no purpose.	Evaluate the need for the meeting. Evaluate whether other methods of delivering information would be better.
Venue is not ready.	Reassess planning procedures.
Equipment is not ready.	Reassess planning procedures.
Meeting fails to begin on time.	This indicates disregard for the value of participants' time. Begin on time, whether or not everyone is present.
Participants do not want to attend meeting or there is poor attendance.	Evaluate whether the meeting is needed, evaluate whether the participants are needed at the meeting, have a clear idea why the meeting is being held, and be able to explain to the participants why their attendance is important. If you cannot do this, then you must ask if you need the meeting. Define attendance expectations
Participants attend meeting unprepared.	Ensure that the agenda is distributed well before the meeting and the participants understand why they are needed and what information they are required to pass on to the group.
Overall planning appears minimal or missing.	Planning ahead of time will increase the level of productivity and decrease the overall meeting time required to meet objectives.
Meeting objectives are unclear.	Begin the meeting by clarifying objectives per written agenda (distributed well ahead of time).
Participants appear to be uninterested or confused.	Make sure the correct participants are present (relevant to the topics under discussion). Continue to clarify goals throughout the discussion. Provide time for questions.
There are interruptions.	Make certain that it is made clear that these are unacceptable. Ensure that your staff knows where you are and that interruptions without good cause should not occur. Limit the length of the meeting. The shorter the meeting, the fewer the interruptions that will occur.
Undercurrent discussions or meetings within meeting occur.	Keep the meeting on track. Inquire of the participants in the undercurrent discussion if there is information that needs to be shared with all. Make it very clear that interruptions are not acceptable; talking during any presentation is also unacceptable. Set up the ground rules from the beginning.
One person dominates the discussion (could be the leader or a participant).	It is the leader's responsibility to ensure that everyone has input and to prevent one person from taking over the meeting; be polite but firm.
The overall discussion appears to stray from the original agenda.	The leader needs to keep the discussion on track and to follow the written agenda.
The meeting runs over the allotted time.	Prior to the meeting, set up realistic time frames; keep the meeting on track and moving forward.
Participants are not clear about what they have been asked to accomplish.	Use action column of agenda to indicate *who* has to accomplish *what* by *when*.
Meeting appears to end without conclusion or decisions.	Make sure a verbal summary is provided and that all participants understand the decisions that were made.
The participants do not receive a written summary in the form of minutes.	A recorder should be identified before or at the beginning of the meeting. Record and distribute written minutes within a day of the meeting; this written documentation serves as a reminder of decisions, pending issues, "to-do" responsibilities, etc.
The leader fails to follow up on meeting decisions or assignments.	This lack of follow-through renders the meeting ineffective. Confirm assignments and due dates and set up a calendar for confirmation of task completion.

KEY POINTS

- Make meetings effective by holding them when:
  - They are necessary.
  - There is a specific goal.
- Ensure that the appropriate meeting format is utilized.
- Ensure that you are familiar with technology being used for the meeting,
- Provide a detailed agenda (or familiarize yourself with the agenda if you are a participant).
- Provide appropriate supporting documentation.
- Expect everyone invited to be prepared and define that expectation.
- Start the meeting on time.
- Keep the meeting on topic.
- Control unnecessary discussions.
- Summarize the meeting at the end with particular reference to the conclusions reached, goals met, and tasks to be completed.
- Stop the meeting on time.
- Promptly provide written minutes.
- Periodically review the necessity for continued meetings.

本书版权归John Wiley & Sons Inc.所有

GLOSSARY

Agenda A list of things to be discussed and acted on at a meeting

Consent agenda A useful tool in managing a meeting, which allows premeeting evaluation of routine material that can be voted on without need for significant discussion or review

Convener The person who calls a meeting and plans to act as the chairperson

Facilitator The person who will assist the convener in planning a meeting

Meeting Interaction between two or more people to discuss a topic of mutual interest or importance

Minutes An official record of the meetings of an organization

REFERENCES

1. **Rogelberg S**, **Shanock L**, **Scott C**. 2012. Wasted time and money in meetings: increasing return on investment. *Small Group Res* **43**:236–245.

2. **Baer D**, **De Luce I**. 2019. $37 billion are lost every year on these 12 meeting mistakes. Insider. https://www.businessinsider.com/37-billion-is-lost-every-year-on-these-meeting-mistakes-2014-4. Accessed July 2023.

3. **Koshy K**, **Liu A**, **Whitehurst K**, **Gundogan B**, **Al Omran Y**. 2017. How to hold an effective meeting. *Int J Surg Oncol N Y* **2**:e22.

4. **Allen JA**, **Rogelberg SG**, **Scott JC**. 2008. Mind your meetings: improve your organization's effectiveness one meeting at a time. *Qual Prog* **41**:49–53.

5. **Mroz J**, **Allen J**, **Verhoeven D**, **Shuffler M**. 2018. Do we really need another meeting? The science of workplace meetings. *Curr Dir Psychol Sci* **27**:484–491.

6. **Karl KA**, **Peluchette JV**, **Aghakhani N**. 2022. Virtual work meetings during the COVID-19 pandemic: the good, bad, and ugly. *Small Group Res* **53**:343–365.

7. **Cook J.** 2017. Laboratory integration and consolidation in a regional health system. *Lab Med* **48**:e43–e52.

8. **Gupta AH**. 14 April 2020. It's not just you: in online meetings, many women can't get a word in. *New York Times*. https://www.nytimes.com/2020/04/14/us/zoom-meetings-gender.html

9. **Bohanon M**. 2020. Gender bias means women are more likely to be silenced online. Insight Diversity https://www.insightintodiversity.com/gender-bias-means-women-are-more-likely-to-be-silenced-online/. Accessed July 2023.

10. **Fosslien L**, **Duffy MW**. 29 April 2020. How to combat Zoom fatigue. *Harvard Business Review*. https://hbr.org/2020/04/how-to-combat-zoom-fatigue

11. **Bailenson JN**. 2021. Nonverbal overload: a theoretical argument for the causes of Zoom fatigue. *Technol Mind Behav* **2**.

12. **Dorfman RF**. 2000. Use a consent agenda to streamline board meetings. *Assoc Manage* **52**:91.

本书版权归John Wiley & Sons Inc.所有

10

Conflict Is Natural and Inevitable
Origins of Conflict
Conflict Resolution Styles
Conflict Management
Equity, Diversity, and Inclusion Considerations
When Conflict Resolution Fails
What the Organization Can Do
SUMMARY
KEY POINTS
REFERENCES

Conflict Management

Christopher Naugler

OBJECTIVES

To define and describe conflict

To discuss the origins of conflict within the clinical laboratory environment

To identify various conflict resolution styles

To review a communication model used in conflict-related discussions

To discuss options when conflict management fails

To identify measures that can be taken by the organization to support an environment in which conflict is identified and managed rather than being ignored

Conflict can destroy a team which hasn't spent time learning to deal with it.

THOMAS ISGAR

Conflict Is Natural and Inevitable

A conflict is simply a disagreement over goals and how to accomplish them. Conflict often begins when a gap develops between what someone expects and the reality that exists (Fig. 10.1). Conflict is all too common in laboratory workplaces. As managers and leaders, we all need to be able to manage conflict in our own relationships as well as assist others in identifying and managing conflicts in the workplace. Few of us have the innate skills necessary to manage conflict, and many managers and leaders would rather avoid dealing with conflict instead of addressing it. However, successful conflict management can be among the most important tools in improving productivity and retaining employees in clinical laboratories. Unresolved conflict occurs when the parties have no power to improve a situation or a decision has been forced upon them that they do not agree with, creating a win-lose outcome. Unresolved conflict always has a negative impact(s) on individuals and organizations, and it takes a heavy economic toll on organizations. It has been reported that the average number of hours spent in workplace conflict in the United States was 2.8 hours per week, translating to US$359 billion in lost time (in 2008 dollars) (1). Prolonged workplace conflict can lead to bullying and other counterproductive behaviors, including purposely wasting company material and supplies, purposely doing one's work incorrectly, and purposely damaging a valuable piece of property belonging to the employer (2).

The first step in addressing conflict is to accept that conflicts are natural in all organizations (3). Moreover, conflict can be beneficial and even necessary

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch10.

本书版权归John Wiley & Sons Inc.所有

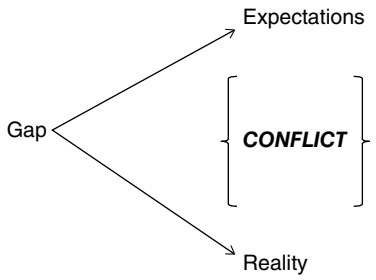


Figure 10.1 How conflict begins.

to the ultimate success of a company. Some of these potential benefits include an improved understanding of the task, team development, and enhanced quality of group decision making (4). The goal of conflict is growth and positive change through agreement to resolution. Conflict is constructive when the involved stakeholders recognize and acknowledge the disagreement and actively work to resolve it. Constructive conflict resolution provides solutions that may involve compromise on both sides to serve the best interests of the organization. Fortunately, conflict management is a skill that can be learned and practiced by any manager or leader.

Origins of Conflict

While diagnosing conflicts may appear to be a matter of rational examination, it is sometimes more of an art than a science. As Madalina (5) states, "A common assumption is that we understand the reasons for conflict and therefore its resolution. However, many conflicts may not be understandable and therefore are not resolvable." Despite this, it is often possible to diagnose the origin of conflict in a clinical laboratory environment by considering the following four common main underlying drivers of conflict: task or organization conflicts, social conflicts, identity and vision conflicts, and conflicts related to achievement (6). Each of these is discussed briefly in the context of the clinical laboratory.

- *Organization conflicts*. Task or organization conflicts are caused by shortcomings in materials, methods, manpower, management, or structure (6). Also known as environmental stresses (7), these can be particularly important and difficult to address in clinical laboratories. The inherent realities of uncertainty and scarcity of resources in healthcare settings create inevitable stress and conflict in and of themselves (7). This is often magnified in laboratories where the lack of public exposure and treatment of the laboratory as a cost center or revenue generator (depending on the laboratory funding model) can create a relentless drive to do more with less.
- *Social and emotional conflicts*. Social and emotional conflicts stem from interpersonal issues between individuals (6). This is a common issue across all companies and health sectors. Sources of these conflicts may include underlying differences in personalities, culture, attitudes, values, and perceptions (8). Often these differences may be difficult to see and difficult for the individuals involved to recognize. Maravelas, in the book *How to Reduce Workplace Conflict and Stress*, advises, "always assume that the other party has multiple hidden constraints or pressures that are shaping his or her behavior" (9).
- *Identity and vision conflicts*. Identity and vision conflicts are problems related to the fundamental direction or function of an organization (6). This is a common and underrecognized source of conflict in clinical laboratories, stemming from fundamental differences in training and worldview between medical/scientific staff and administrators. Indeed, pathologists and clinical doctoral scientists have ethical, moral, and legal obligations that may not be shared by their administrative and managerial counterparts (10). Shale refers to this as "an integral paradox" which can create lasting conflicts in healthcare organizations (11). Although this source of conflict can share features with task or organization conflicts, it is important to recognize that the root cause is often related to professional identity. Laboratory physicians must abide by the Hippocratic oath and the fundamental principles of medical ethics, and they have a moral and ethical obligation to advocate for patients and public health. Inherent in this view is that professional judgment and autonomy are fundamental to good patient care. In contrast, managers are generally trained in a business environment and believe that standardized approaches are a better path to improve safety and healthcare system performance (10, 12–14). Conflicts between medical and administrative groups are often unresolvable until each side recognizes that the other is acting in accordance with their own differing philosophy.
- *Achievement conflicts*. Conflicts related to achievement arise when individuals cannot achieve their interests and goals (6). This is another common source of conflict in resource-constrained settings and may arise due to the inability of an individual to advance through the generally strict hierarchy of laboratory management and leadership roles.

Within these broad categories, another aspect of workplace dynamics must be understood, and that is power. Power is not generally evenly distributed at work. The work environment is almost always set up in a stratified hierarchy. That "pecking order" may be established in

本书版权归John Wiley & Sons Inc.所有

formal or informal ways (organizational charts versus how things really get done), but power is not evenly distributed to all the staff. Even among members of the same profession, power is not equalized. Among physicians, for example, seniority, specialty, tenure, political connections, grant funding, research projects, gender, race, and several other overt and hidden criteria impact who has power and who is expected to yield to it.

Among laboratory technical staff, power differentials can occur based on differences in formal or informal training and statewide or national credentials, as well as length and type of experience. When offices or companies merge, political alliances, seniority, and reporting relationships have to be renegotiated in combined offices. These and myriad other potential conflicts need to be anticipated, addressed, and resolved. Otherwise, the underlying issues build until they erupt into hostile differences. Common causes of conflict include the following.

- Incompatible goals
- Poor communication
- Style of supervision
- Different ideas about task achievement
- Different perceptions
- Different values and philosophies
- Personality differences
- Work assignments
- Approaches to change
- Competition

Conflict is going to exist. These major categories of conflict must be identified and addressed before they build into major disruptions to the office or laboratory environment.

Conflict Resolution Styles

Numerous models exist for assessing the approach to conflict management. These generally boil down to five distinct ways of handling conflict (15). Although you may have a particular style that comes naturally to you, it is important to remember that individual conflict management styles may have specific advantages in particular circumstances (16), and the ability to move between these as dictated by the specific circumstances can be a valuable skill.

- *Accommodate*: this approach may be the best tactic when maintaining a good working relationship outweighs other considerations (7).
- *Compete*: use this approach in circumstances where maintaining a close supportive relationship is unimportant or there is a sense of urgency (7).

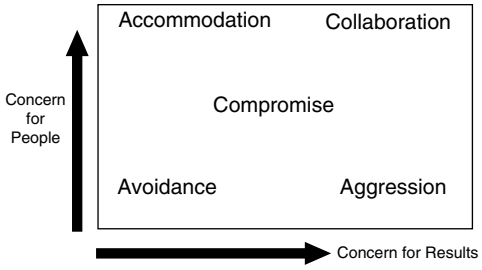


Figure 10.2 Conflict resolution styles based on task or people concerns.

- *Collaborate*: this approach may be best when the issues at hand are critical, a continuing relationship is important, and time is not pressing (7).
- *Compromise*: consider using this approach when the issues are complex and important and there are no obvious best solutions.
- *Avoid*: this may be the best course of action when the issue is of low importance and there are no strong interpersonal reasons to become involved (7).

These styles are illustrated on a continuum of concern for people and concern for results in Figure 10.2.

Individuals have different styles of approaching conflict and conflict resolution. Conflict style inventories are widely available and may be useful in promoting self-awareness regarding the way that conflict is approached by an individual (16). The Thomas-Kilmann instrument is one widely used self-assessment instrument (17). The instrument creates a conflict style inventory by asking the reader to choose between a series of paired choices to identify the five styles of conflict resolution listed above. Performing a conflict style inventory as part of a team-building exercise may be a useful way to build awareness of conflict resolution styles within a team.

Differences in conflict resolution styles may also be related to the underlying personality characteristics of the individuals involved. The most widely employed personality taxonomy is the Five Factors model, also known as the Big 5 (Table 10.1). These personality traits often show significant associations with job satisfaction (18, 19). A recent meta-analysis of studies addressing personality traits and conflict resolution styles showed that an avoiding style was positively related to neuroticism and agreeableness; both compromising and integrating styles were positively

Table 10.1 Big 5 personality traits, often referred to by the acronym OCEAN or CANOE (41)

Extraversion (outgoing/energetic vs. solitary/reserved)
Agreeableness (friendly/compassionate vs. critical/rational)
Openness to experience (inventive/curious vs. consistent/cautious)
Conscientiousness (efficient/organized vs. extravagant/careless)
Neuroticism (sensitive/nervous vs. resilient/confident)

本书版权归John Wiley & Sons Inc.所有

associated with agreeableness, extroversion, openness to experience, and conscientiousness; and an obliging style was positively associated with agreeableness (20). Although individual personality characteristics will rarely be known, they can theoretically be predicted with reasonable accuracy (19, 21–23). The important point to remember is that underlying personality traits of individuals involved may play an important role in how they approach conflicts.

Emotional intelligence is yet another factor affecting conflict management strategies. Emotional intelligence can be defined as the ability to monitor the emotions of oneself and others, discriminate among the positive and negative effects of emotion, and use this information to guide one's thinking and actions (24). Higher emotional intelligence is positively associated with team performance but not with performance on individual tasks (25). Individuals with higher levels of emotional intelligence are more likely to engage in collaborative conflict resolution, while lower emotional intelligence is associated with the use of competitive and avoidance strategies (26, 27).

Conflict Management

An entire leadership training industry has been built around teaching conflict management skills. Although administrators with business training have often been exposed to conflict management principles, for physicians, conflict management, like all aspects of interpersonal competence, is "usually obtained through a hidden curriculum of on-the-job training, or not at all" (15). This is despite recommendations that conflict management training be mandatory for physicians during residency (28). This is supported by considerable evidence that conflict resolution (29, 30) and mediation (31) training is beneficial for healthcare workers.

Table 10.2 Basic principles common to various models of conflict management (4)

Conflict is inevitable and may result in positive or negative consequences depending on it is managed.
Results are likely to be better with active engagement rather than avoidance.
People must be motivated to address conflict.
Behavioral, cognitive, and emotional skills can be acquired.
Emotional skills require self-awareness.
The environment for conflict resolution must be neutral and feel safe.

The complexity of various approaches cannot be addressed in a brief review; however, various approaches share a number of characteristics. The basic principles of conflict management common to various models are summarized by Overton and Lowry (4) (Table 10.2).

However, the various conflict resolution styles and principles of conflict management may seem somewhat academic in the "heat of the moment" when you are dealing with an active conflict. This is especially true if you are personally or emotionally involved in the conflict. For this reason, a systematic approach is often an important tool. One such approach has been proposed by Zucker (32) and can be written on a card and taken to conflict resolution sessions as a memory aide. The steps are listed in Table 10.3.

A novel proactive approach has been suggested by Samuel (33) in the form of "interaction agreements". The idea is that team members create an agreement covering:

1. How information will be shared
2. How team members will be supported by one another
3. How decisions will be made
4. How trust will be maintained

These agreements can be reviewed regularly at team meetings and can form a mechanism for holding other team

Table 10.3 Simplified approach to conflict management (modified from reference 33)

Step	Action	Comments
1	Invite the other person to have a conversation about the issue, with the goal being a meaningful two-way discussion leading to a successful resolution.	*Identify the source of the conflict*. Is it one major issue? Has there been simmering hostility or frustration over time between the parties? Do the parties involved want it resolved? Can it be resolved? What is the goal of each party?
2	Ask for the others' perspectives and paraphrase what you hear. Give your perspective and highlight similarities and differences.	Have participants state their goals. What are the areas of agreement or overlap? Have each person paraphrase the other's points. It encourages them to listen to each other and helps avoid a focus on being "right." Focus on what behaviors are getting in the way of effective workplace interaction.
3	Discuss the intent and impact of actions. Try to determine the true issues at hand for each party (refer to the origins of conflict discussed above).	*Identify the players*. What are the personalities? What is their history? Did they ever get along? Do you want to keep both people employed? Why? Do they know that?
4	Agree on solution(s).	After exploring options, select the ideas that are workable and can be immediately implemented.
5	Plan how you will implement the agreed-to solution(s).	If managers and employees were empowered and trained to resolve conflict, it would seldom be necessary to seek outside help. However, do not be afraid to ask for assistance from an internal human resources department if you have one, or from an external consultant trained in conflict resolution.

本书版权归John Wiley & Sons Inc.所有

members accountable for their actions as well as providing a road map for resolving conflicts when they occur.

It may also be useful to follow a communication model when engaging in confict-related discussions. One such model is the give-get-merge-go (GGMG) model proposed by psychologist Robert Carkhuff (34). The model allows all parties to speak, be heard, and negotiate a mutually agreeable resolution and to implement it. With the GGMG model, all parties involved need to share information about what bothers them and what their goals are. This is the "give" and "get" portion of the model. The parties need to listen and pay attention to what each person wants. In the midst of the interaction, there is an opportunity to find overlap in their goals. This is the "merge" step. Once overlapping goals are identified, the parties take steps to reach the newly agreed-upon goals. The "go" piece is the final step that leads to conflict resolution.

Equity, Diversity, and Inclusion Considerations

Respecting diversity among staff and being inclusive of all staff regardless of ethnicity, age, etc., are key priorities for healthcare systems, to provide the best possible service to diverse patient populations (35). Efforts to improve diversity and inclusion in medicine have been recently undertaken by several organizations, including the Institute of Medicine (IOM) and the Liaison Committee on Medical Education (LCME) (36). These principles are also of key importance in the clinical laboratory. As a recent editorial stated, "Diversity is integral to sustaining a successful laboratory environment, and it continues to gain ground as a necessary component for providing the gold standard of patient care" (37). Part of understating, embracing, and promoting diversity in the workplace is recognizing that individuals from different cultural backgrounds may have inherently different approaches to the same issues.

In particular, conflict management is greatly influenced by social culture (38). For example, a study of American and Chinese business managers found that Chinese managers relied more on an avoiding style, while American managers relied more on competing or adversarial styles (38, 39). Another study of Chinese and American managers demonstrated that hostility and vengefulness were important elements for American managers, while embarrassing the colleague and teaching a moral lesson were important elements for Chinese managers (40). An overarching principle appears to be that individualistic cultures often have confrontational approaches to conflict management and collectivistic cultures may prefer strategies that are harmony inducing.

There is much more to be learned about the importance of equity, diversity, and inclusion in conflict resolution. As clinical laboratories work toward meaningful integration of these concepts, an understanding of the cultural, ethnic, and religious influences on conflict management will become increasingly important.

When Conflict Resolution Fails

Despite their best efforts, there may be cases when the parties fail to resolve the conflict. This may be due to employee substance abuse problems, such as drug or alcohol dependency, or to employees who refuse to comply with the terms of a conflict resolution agreement. Alternatively, an employee may not have the skills and capabilities to succeed on the job. The conflict between the job performance levels needed and those demonstrated must be resolved by formal personnel actions. Internal progressive disciplinary processes need to be applied. Progressive disciplinary steps generally include an oral warning, a written warning, a final written warning, suspension, and finally termination.

What the Organization Can Do

There are several measures that can be taken by the organization to support an environment where conflict is managed instead of ignored. They include the following.

- Provide in-service workshops for staff at all levels to teach conflict resolution skills.
- Provide training to all new employees as a part of new-employee orientation programs. Technical skills are essential, but if individuals cannot resolve conflict, the technical skills can be overshadowed by interpersonal troubles.
- Have regular "letting off steam" meetings. Structure lunch meetings where problems can be addressed and resolved. Problems can be submitted anonymously and a team approach to resolving problems can be used.
- Encourage staff at all levels to bring up conflicts with coworkers and empower them to address them to the point of resolution.
- Have managers and supervisors at every level serve as role models in addressing and resolving conflict.
- Provide ongoing support through the human resources department, if the organization has one, or outsource the role to a consultant to provide training and guidance for resolving conflict.
- Provide an employee assistance program for employees experiencing job or life stress to resolve issues that contribute to high levels of conflict.
- Provide posters, newsletters, and other visible reminders that resolving conflict is important to the organization.
- Focus on identifying, analyzing, and resolving conflicts so that the quality of life at work is the highest it can be. This enhanced quality of life at work can also serve to attract and retain the best employees.

本书版权归John Wiley & Sons Inc.所有

Create an organizational culture that supports and encourages staff to address conflict and bring it to the attention of management. Conflict is inevitable. Resolving it must be, too, in order for productive and meaningful work to occur.

SUMMARY

Conflict is natural and inevitable, and yet it is often poorly managed, resulting in tremendous costs to companies. Conflict in clinical laboratories may arise from issues with tasks or organization, social and emotional differences, identity and vision problems, and issues related to achievement. Differing goals and worldviews between medical/scientific staff and administrators are a common source of conflict in clinical laboratories. Individuals have differences in conflict resolution styles, often related to underlying differences in basic personality traits. Numerous conflict management models exist and have many common elements. A simplified model is presented. As clinical laboratories work toward meaningful integration of equity, diversity, and inclusion, an understanding of the cultural, ethnic, and religious influences on conflict management will become increasingly important.

KEY POINTS

- Conflict is natural and inevitable.
- The origins of conflict in clinical laboratories are often identifiable and even predictable.
- Individuals have distinct conflict resolution styles, and each style may be useful in particular circumstances.
- Innate personality traits, often described by the Five Factors model, are associated with distinct conflict resolution styles.
- Conflict management models often share may of the same basic elements.
- As labs integrate equity, diversity and inclusion concepts into practice, an understanding of the cultural, ethnic and religious influences on conflict management will become increasingly important.

REFERENCES

1. **CPP, Inc**. 2008. CPP Global human capital report. Workplace conflict and how businesses can harness it to thrive. https://www.themyersbriggs.com/-/media/f39a8b7fb4fe4daface552d9f485c825.ashx. Accessed 23 August 2023.

2. **Ayoko OB, Callan VJ, Härtel CEJ**. 2003. Workplace conflict, bullying, and counterproductive behaviors. *Int J Organ Anal* **11**:283–301.

3. **Cokins G.** 2009. *Performance Management. Integrating Strategy, Execution, Methodologies, Risk and Analytics*, p 101. John Wiley & Sons Inc, Hoboken, NJ.

4. **Overton AR, Lowry AC**. 2013. Conflict management: difficult conversations with difficult people. *Clin Colon Rectal Surg* **26**:259–264.

5. **Madalina O.** 2016. Conflict management, a new challenge. *Procedia Econ Finance* **39**:807–814.

6. **Strack van Schijndel RJM, Burchardi H**. 2007. Bench-to-bedside review: leadership and conflict management in the intensive care unit. *Crit Care* **11**:234.

7. **Lemieux-Charles L.** 1994. Physicians in health care management: 10. Managing conflict through negotiation. *CMAJ* **151**:1129–1132.

8. **Beheshtifar M, Zare E**. 2013. Interpersonal conflict: A substantial factor to organizational failure. *Int J Acad Res Business Social Sci* **3**:400.

9. **Maravelas A.** 2005. *How to Reduce Workplace Conflict and Stress*, p 165. The Career Press Inc., Franklin Lakes, NJ.

10. **Church DL, Naugler C**. 2019. Benefits and risks of standardization, harmonization and conformity to opinion in clinical laboratories. *Crit Rev Clin Lab Sci* **56**:287–306.

11. **Shale S.** 2008. Managing the conflict between individual needs and group interests—ethical leadership in health care organizations. *Keio J Med* **57**:37–44.

12. **McDonald R, Waring J, Harrison S**. 2006. Rules, safety and the narrativisation of identity: a hospital operating theatre case study. *Sociol Health Illn* **28**:178–202.

13. **Mannion R, Exworthy M**. 2017. (Re) making the procrustean bed? Standardization and customization as competing logics in healthcare. *Int J Health Policy Manag* **6**:301–304.

14. **Waring J, Allen D, Braithwaite J, Sandall J**. 2016. Healthcare quality and safety: a review of policy, practice and research. *Sociol Health Illn* **38**:198–215.

15. **Saltman DC, O'Dea NA, Kidd MR**. 2006. Conflict management: a primer for doctors in training. *Postgrad Med J* **82**:9–12.

16. **Austin Z, Gregory PA, Martin C**. 2009. A conflict management scale for pharmacy. *Am J Pharm Educ* **73**:122.

17. **Thomas KW, Kilmann RH**. 1978. Comparison of four instruments measuring conflict behavior. *Psychol Rep* **42**:1139–1145.

18. **Judge TA, Heller D, Mount MK**. 2002. Five-factor model of personality and job satisfaction: a meta-analysis. *J Appl Psychol* **87**:530–541.

19. **Staw BM, Cohen-Charash Y**. 2005. The dispositional approach to job satisfaction: more than a mirage, but not yet an oasis. *J Organ Behav* **26**:59–78.

20. **Tehrani HD, Yamini S**. 2020. Personality traits and conflict resolution styles: a meta-analysis. *Pers Individ Dif* **157**:109794.

21. **Gavrilescu M, Vizireanu N**. 2018. Predicting the Big Five personality traits from handwriting. *J Image Video Proc.* **2018**:57.

22. **Azucar D, Marengo D, Settanni M**. 2018. Predicting the Big 5 personality traits from digital footprints on social media: a meta-analysis. *Pers Individ Dif* **124**:150–159.

23. **Golbeck J, Robles C, Turner K**. 2011. Predicting personality with social media, p 253–262. CHI '11 Extended Abstracts on Human Factors in Computing Systems.

24. **Salovey P, Mayer J**. 1990. Emotional intelligence. *Imagin Cogn Pers* **9**:185–211.

本书版权归John Wiley & Sons Inc.所有

25. Jordan PJ, **Troth AC**. 2004. Managing emotions during team problem solving: emotional intelligence and conflict resolution. *Hum Perform* **17**:195–218.

26. Jordan PJ, **Troth AC**. 2002. Emotional intelligence and conflict resolution: implications for human resource development. *Adv Dev Hum Resour* **4**:62–79.

27. Başoğul C, **Özgür G**. 2016. Role of emotional intelligence in conflict management strategies of nurses. *Asian Nurs Res Korean Soc Nurs Sci* **10**:228–233.

28. Rosenman ED, **Vrablik MC**, **Charlton PW**, **Chipman AK**, **Fernandez R**. 2017. Promoting workplace safety: teaching conflict management and de-escalation skills in graduate medical education. *J Grad Med Educ* **9**:562–566.

29. Mustafa S, **Stoller JK**, **Bierer SB**, **Farver CF**. 2020. Effectiveness of a leadership development course for chief residents: a longitudinal evaluation. *J Grad Med Educ* **12**:193–202.

30. Wolfe AD, **Hoang KB**, **Denniston SF**. 2018. Teaching conflict resolution in medicine: lessons from business, diplomacy and theatre. *MedEdPORTAL* **14**:10672.

31. Saulo M, **Wagener RJ**. 2000. Mediation training enhances conflict management by healthcare personnel. *Am J Manag Care* **6**:473–483.

32. Zucker D. 2012. Tools for productively managing conflict. *J Investig Med* **60**:776–778.

33. Samuel M. 2006. *Creating the Accountable Organization. A Practical Guide to Improve Performance Execution*, p 126. Xephor Press, Katonah, NY.

34. Carkhuff RR. 1983. *The Art of Helping*, p 14–27. Human Resource Development Press, Amherst, MA.

35. Stanford FC. 2020. The importance of diversity and inclusion in the healthcare workforce. *J Natl Med Assoc* **112**:247–249.

36. Holladay EB. 2019. Diversity in the laboratory. *Crit Values* **12**:3.

37. Morris MW, **Williams KY**, **Leung K**, **Larrick R**, **Mendoza MT**, **Bhatnagar D**, **Li J**, **Kondo M**, **Luo JL**, **Hu JC**. 1998. Conflict management style: accounting for cross-national differences. *J Int Bus Stud* **29**:729–747.

38. Leung K, **Lind EA**. 1986. Procedural justice and culture: effects of culture, gender, and investigator status on procedural preferences. *J Pers Soc Psychol* **50**:1134–1140.

39. Doucet L, **Jehn KA**, **Weldon E**, **Chen X**, **Wang Z**. 2009. Cross-cultural differences in conflict management: an inductive study of Chinese and American managers. *Int J Confl Manage* **4**:355–376.

40. Leung K, **Au Y**, **Fernandez-Dols JM**, **Iwawaki S**. 1992. Preference for methods of conflict processing in two collectivistic cultures. *Int J Psychol Spec Issue* **27**:195–209.

41. Roccas S, **Sagiv L**, **Schwartz SH**, **Knafo A**. 2002. The Big Five personality factors and personal values. *Pers Soc Psychol Bull* **28**:789–801.

本书版权归John Wiley & Sons Inc.所有

11

Introduction

The Case for Change Management
Definition of Change • The Psychology of Change • Why Change Management Is Important • Sources of Change • The Need for Change

Models of Change Management
The Kotter Model • The ADKAR Model

Supporting Laboratory Staff Through Change
Actions Leading to Successful Change • Managing Resistance • Auditing and Reinforcing the Change

SUMMARY

KEY POINTS

GLOSSARY

REFERENCES

APPENDIX

Leading People Through Change in Pathology and Laboratory Medicine

Gabriel E. Ayala

OBJECTIVES

To define change

To discuss the reasons why change management is important

To discuss the models of change management

To identify the necessary steps required to manage change effectively

To recognize and understand how to manage resistance to change

To understand the importance of monitoring and reinforcing changes once implemented

People don't buy what you do; they buy why you do it…

Simon Sinek

When people talk about change management, they often start talking in clichés. They may say things such as "change is unavoidable" or "change is a constant." These platitudes about change, although true, can hide how difficult change can be when not managed properly. After more than 20 years of experience in the field of organizational development and effectiveness, I can attest to the fact that change management is a widely neglected practice in a variety of industries. For some leaders, change management is a process of communicating things to the staff so they "know" what may happen in the future. Usually, these communications are very precise in two main components: the *what* and the *when*. There is a perception by some leaders that informing employees and staff is sufficient to prepare them for the change ahead. This perception might have a second negative component, which is the impression that good changes do not require as much effort as negative changes. This will eventually impact staff negatively, as they will not be supportive of the change.

Today, laboratory medicine does not escape the reality of change. At the time of writing, the world remains impacted by severe acute respiratory coronavirus 2 (SARS-CoV-2), the agent of coronavirus disease 2019 (COVID-19). The pandemic, which started with the first known case in December 2019, not only had a severe impact on how we live but also required organizations and, our subject, laboratories around the world to adapt at an astonishing speed.

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch11.

本书版权归John Wiley & Sons Inc.所有

We can name a few aspects of laboratory medicine that COVID-19 changed. Microbiology and public health departments around the world had to start testing for the virus in significant numbers, which stretched their capacity in unthinkable ways, while continuing to provide other services to patients. Staff had to work around the clock to ensure that patients got their results in time, which in turn provided an effective way to arrest the further spread of the virus. This change not only applied to departments dealing with the virus but also applied to other laboratory departments, which had to lead staff in the effort to fight the pandemic while continuing to provide their expertise and service in their own areas.

The Case for Change Management

Definition of Change

The first order of business when justifying the need for change management is to define change. Furthermore, it is important to define change in the context of organizations. If we think about organizations, we can present them as ecosystems or an aggregate of systems. Depending on the organization, we can identify information systems, specific subject matter technology, standard operating procedures, legislation, best practices associated with the industry, etc. Arguably, the most important subsystem of the organization is the human component. Ultimately, it is the people who manage all the technology, the work processes, and the context of the work. As a result, all organizations must make efforts to ensure that their workforce is functioning properly. This applies of course to moments in which the workforce is being tested by change. Caldwell presented a simple and yet comprehensive definition of organizational change. He defined it as a process in which stability is disturbed and a period of instability ensues, which ends at a stage of subsequent relative stability (1). This definition is based on the seminal work by Kurt Lewin, in which he defined the three stages as *unfreezing, change,* and *refreezing* (2). This classical model has served as foundational for all contemporary thought in change management.

In my experience, the unfreezing phase is when the "heavy lifting," from a motivational perspective, must occur to achieve positive results as part of the change. This stage is where staff and physicians will have the highest number of questions and the greatest sense of uncertainty and ambiguity.

The Psychology of Change

We can use an analogy that, while it runs the risk of oversimplifying the construct of the psychology of change, serves as a safe and noncontroversial illustration of what happens to human beings when dealing with change. Imagine that you are driving your usual route to work, you depart at the same time as you routinely do. Because you were a little bit behind in your schedule, you did not check the news. While driving, you encounter construction ahead with the inevitable detour following it. You start feeling discomfort, potentially a moment of anger, and then suddenly you realize that you must figure out a new way to get to work. You are not familiar with the imposed detour; you must pay extra attention to where you are going while figuring out what time you will arrive at work, and your entire day seems to be affected by this small change in route—or at least, that is your perception.

Another way to illustrate what happens to us in times of change is a simple exercise that I use with students when teaching about change. I ask them to fold their arms and tell me how they feel. Then, I ask them to fold their arms again but with the other arm on top. When I ask them how they feel, they tend to provide responses such as "uncomfortable" or "awkward." After that I ask them to write their name on a piece of paper, then I ask them to do it again with their other hand. When I do this, I see people struggling but they complete the task. Then we talk about how the speed of execution and the quality of the task diminished after the change, but they still completed the task. Through these two exercises, which are well known among colleagues in organizational psychology and organizational effectiveness, I illustrate the feelings that we experience when we go through change. These feelings or emotions are like the so-called fight-or-flight instinct. The body prepares to defend itself, norepinephrine runs high, and we just feel inadequate. This explains why so many people experience resistance to change. It is not their fault, it is not because they are bad professionals, it is simply human nature. Later in this chapter, I discuss potential reasons for resistance, but the foundation is still the feeling of strong discomfort experienced when people need to change the way they work.

Why Change Management Is Important

Going through change is significantly uncomfortable, even if the change is in a positive direction. Humans tend to form habits, and when those habits are disturbed, people struggle. Addressing these struggles to support the success of staff and physicians during times of change is the main justification for focusing on change management strategies. Prosci, Inc., an organization which is world renowned for its expertise in change management, maintains that there are five tenets that emphasize the need for change management (3): (i) we change for a reason; (ii) organizational change requires individual change; (iii) organizational outcomes are the collective result of individual change; (iv) change management is an enabling framework for managing the people side of change; and (v) we apply change management to realize the benefits and desired outcomes of change. These five tenets presented by Hiatt and Creasy illustrate the need for a

本书版权归John Wiley & Sons Inc.所有

disciplined and people-focused approach to dealing with change (3). The reason why organizations fail to manage change properly is that they focus not on supporting the people but on communicating to the people and managing the change solely as a project. People fail to adopt new work processes or modern technologies because their reactions to change have not been managed, the supporting structures have not been created, and people are left with a feeling that change was done to them.

Sources of Change

This brings us to an exploration of the sources of change in organizations. Change is an imperative caused by the inability of the current way of working to deliver the results that the organization needs to deliver. In the case of healthcare, patient care needs make it imperative for laboratories to constantly respond by providing new means of service delivery. In my experience, the main sources of change are (i) new government mandates or legislation changes affecting the organization; (ii) financial constraints, such as budget limitations or changes in the economy; (iii) the emergence of new technologies; (iv) innovation in expertise; (v) competitiveness requirements; and (vi) changes in societal needs and requirements as they pertain to the organization. These sources of change imply that change is not an option but an imperative. Therefore, all organizations, and their individuals, must change at some point, or several points.

The Need for Change

As Hiatt and Creasy (3) put it, all organizations and individuals need to ask themselves, what is the risk of not changing? In laboratory medicine, there are intrinsic risks associated with a lack of readiness to change. The first one is applicable for all businesses regardless of whether they are for profit or not for profit. That is the lack of responsiveness to trends in the needs of the client—in this case, the patients. At a personal level, there is a risk of being left behind by the organization if one refuses to change. While this may not impose a risk in terms of employability in some cases, it detaches the person emotionally from the organization. Another risk is not being able to deliver the results the organization needs to deliver as a result of not adapting to changes in medicine, technology, and patient care. This creates the psychological impulse required to engage in the change.

Models of Change Management

Two major models of change management are presented here: the Kotter model and the Prosci model, which is known as the ADKAR model (4). While there is a variety of models in the field, these two have a particular and important focus on the people aspect of change, which, as explained in the section above, is the focus of current best practices in organizational change management.

The Kotter Model

John Kotter's work has evolved throughout the decades, and he is one of the most recognized authors addressing the people side of change. In his model, he proposes eight steps of change management for success in organizations (5, 6). The steps are as follows: create a sense of urgency, build a guiding coalition, form a strategic vision and initiatives, enlist a volunteer army, enable action by removing barriers, generate short-term wins, sustain acceleration, and institute change.

Creating a sense of urgency is related to the *why* of the change. It is about identifying the change as an opportunity that appeals to the hearts and minds of individuals in the organization. The guiding coalition is about identifying individuals across the organization at any level of the hierarchy to be the conduits of information. The third step implies the need for a compelling vision of success. It is not only about information but about communicating what success will look like when the change is complete. It provides a clear view of the future. Enlisting a volunteer army involves asking people in the organization to join the change efforts, volunteering to mentor others, and making sure they are free to provide their expertise. Enabling actions by removing barriers makes sure that old processes are removed and new processes are in place that facilitate the team's jobs; it also involves providing resources where possible and ensuring that things that are under the control of the change team are managed properly.

Generating small wins is all about deconstructing the work into achievable tasks. Leaders are responsible for setting milestones that are achievable along the way. Leaders need to motivate their teams by providing unambiguous wins, as these motivate people to continue. Sustaining acceleration connects to the first step. Urgency must not ebb along the way. If the vision and urgency are not constantly in the minds of staff, momentum is easily lost. Finally, instituting change means that the new way of working becomes part of the identity of the organization. Connection of the new behaviors and processes with the success of the organization achieves this goal.

The ADKAR Model

Widely used in organizations globally, including healthcare, the ADKAR model, developed by the founders of Prosci, Inc., represents a methodological focus on the people side of change. Many organizations focus on project management as a primary way of leading change. This implies creation of a project plan, allocation of resources, and a well-planned and -executed communication strategy. However, Prosci would argue that while project planning is crucial, without taking care of the people side of change,

本书版权归John Wiley & Sons Inc.所有

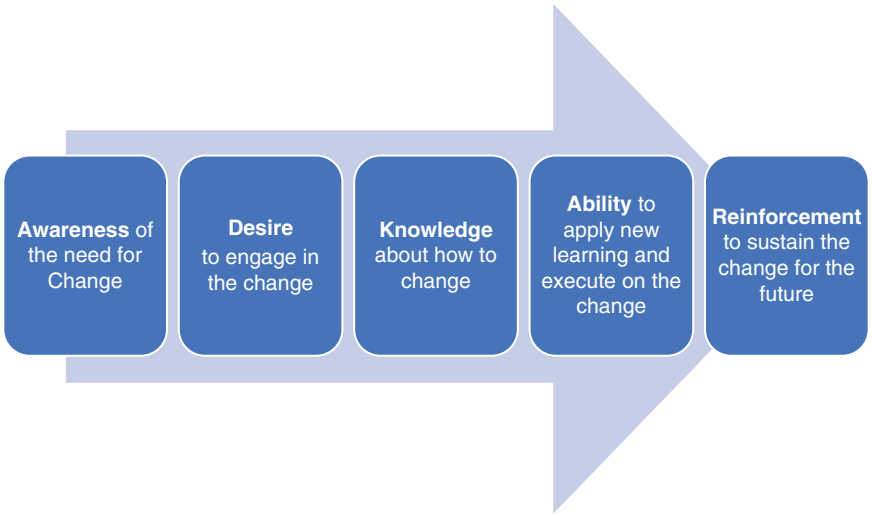


Figure 11.1 Visual representation of the ADKAR Model

most projects will ultimately fail. "ADKAR" (4) is an acronym that signifies a sequential model to help people go through change and the factors that affect change (Fig. 11.1): the letters stand for "awareness, desire, knowledge, ability, and reinforcement." Let us explore each of the stages of this model.

Awareness. Awareness is the first stage of the model. It is at this stage that many leaders get it wrong. Most leaders think that they need to communicate what the change is or even when it is happening. However, the awareness that the model refers to is awareness of the need for change. In other words, to build awareness among the staff, leaders need to communicate the *why* of the change. In his research, Hiatt (4) reports that when people start perceiving that there is a change, the first response is to ask why. Why are we changing? Why now? Is there anything wrong with what we are doing now? What happens if the change is not completed? These are just some of the questions employees start asking. But the question that all staff members will ask is the proverbial WIIFM, or "What's in it for me?" Consequently, at the initiation of change, leaders need to be prepared to communicate the *why* and to answer questions about it.

Desire. Desire is the second stage of the model. Awareness is a prerequisite for building desire. One thing that leaders must understand is that desired change is not process driven, but it is an act or action reflecting the will of individuals. Imagine that a laboratory changes its equipment for the latest technology available globally. This change from all objective perspectives is a step in the right direction in terms of best practices. However, the new equipment will not be used or effectively used by the staff unless they want to do it—that is, unless they buy the premise that the new equipment is better for the laboratory and them. The will to change is influenced in the model by four factors: (i) the nature of the change and WIIFM, (ii) the context in which the change is occurring, (ii) the personal situation of staff, and (iv) the intrinsic motivation. The context is crucial; it is essential to discuss with staff questions such as how much change is already going on, whether the change proposed aligns with the vision of the organization, and how resources are going to be allocated. The personal situation is also important. For example, a person at the end of their career may not want to invest the effort required to change. The perception of job security may also influence the desire to change. Leaders need to know the individual realities of their staff to be able to support them during and after the change. Motivation is also important, and this has to do with the desire for self-actualization of individuals. Are they motivated to invest the extra effort that is needed to change? This question depends on the organizational climate and the levels of engagement.

Knowledge. The third stage is knowledge, and for the purpose of this chapter, it is discussed together with ability. Once individuals decide that they want to engage in the change, they would need to know how to change. This is related to training. Staff need to acquire the new skills required for the successful implementation of the change. Also, they need to understand the new processes and their roles in them. However, training is not sufficient without the development of new abilities.

Ability. Ability is a function of transferring what is learned in training to the execution of the tasks in the actual job. Individuals develop abilities at different

本书版权归John Wiley & Sons Inc.所有

paces and with different rates of success. Therefore, it is crucial to provide the coaching support necessary.

Reinforcement. Reinforcement is the last stage. There needs to be meaningful recognition for success in the implementation of the change. Also, people need to know they can take risks while trying to change and not be fearful of negative consequences. Feedback from employees is essential for leaders to understand how any change is progressing from the point of view of the staff. One final aspect of reinforcement is that individuals need to start treating the new as old. This means that as soon as possible, the organization needs to move away from the "old" ways. The new is the present, and the old needs to be discarded. As expressed above, this is a sequential model: individuals cannot have the desire to do something they are not aware of, they cannot train for something they do not want to do, they cannot develop new abilities without the necessary training and coaching support, and organizations cannot reinforce new behaviors and abilities when they are not recognized.

Supporting Laboratory Staff Through Change

One of the main intents of this chapter is to show that change management is not a matter of processes and procedure, and it is not a matter of going through the motions of communicating change messages and ticking through checklist items. Change management is about supporting the people who need to be part of the change. It is argued above that initial resistance or at least doubt is a natural reaction to change. Thus, it is crucial as the first step to suspend any judgment about the staff. In most cases, resistance or doubt is not about the character of individuals but about being humans. In the change literature, terms such as *early adopters* or *laggards* can easily be found. However, while having an awareness of who is ahead or who is behind in the change can be useful, labels are not helpful if leaders want to bring people together around the change proposed.

Actions Leading to Successful Change

Both Kotter and Prosci, as well as many others, suggest that the first step is to positively influence the motivation or desire to change. In my experience, some leaders are hesitant about sharing the *why* of a change because they operate on a need-to-know basis. This is more evident when the cause of the change is negatively perceived (e.g., budget cuts). Hiding negative reasons for change is a mistake, because the leaders are missing a chance to represent the change as an opportunity even under negative circumstances. It is important to remember that in laboratory medicine, the main concern is to serve patients, and laboratories need to find ways to continue doing that. Therefore, the *why* and the context of the change should be the first message discussed with staff. Taking into consideration the models presented in this chapter and my experience in the field of organizational effectiveness, there are certain actions that all leaders must execute to have a successful change in their organization (Table 11.1). These actions are not in any particular order.

Table 11.1 Actions to lead change

Step	Action
1	Raise awareness by communicating the *why*
2	Communicate the boundaries of the change
3	Create a change management network
4	Equip midlevel leaders with tools to communicate with their staff
5	Provide training and coaching
6	Communicate, communicate, and then communicate some more
7	Manage resistance

- *Action 1* is to raise awareness by communicating the *why*. This action is discussed above.
- *Action 2* is to communicate the boundaries of the change. This is related to what is changing and what is not changing. This provides some direction to the staff.
- *Action 3* is to create a change management network. Leaders can identify staff that may be able to volunteer to serve as change agents. The key is to identify people that can bring back to the change management team what they are hearing from the staff. This has two purposes. The first one is to provide a voice to employees to communicate their concerns and their positive ideas about the change so leadership can address them. The second purpose is to provide information to leadership about any misunderstanding about the change so it can be immediately rectified. However, organizations will fail at this action if they do not provide these networks with information to disseminate as well. It is not only about collecting feedback from the staff but also about providing the agents of the network with information to share with their peers. This helps minimize the presence of rumors.
- *Action 4* is to equip midlevel managers with information toolkits so they can translate the big organizational messages into meaningful employee-level messages for their staff. When staff are curious about how the change affects them and their work, they do not want to hear from the CEO or Human Resources (HR); they want to hear from their direct supervisor. It is their immediate leaders who know their work best and can understand and address their concerns.
- *Action 5* is to provide training and coaching support. As discussed below, one of the reasons that people

本书版权归John Wiley & Sons Inc.所有

resist change is because of the perception that they do not have the skills or abilities to work according to new processes or technology. Hence, organizations must provide enabling structures, such as training and coaching, so that individuals can develop the skills needed. One thing to take into consideration is that the staff are subject matter experts in their roles, so it is advisable and almost prescriptive to include them in the design of the training and engage them to act as mentors to others.

- *Action 6* is to communicate, communicate, and then communicate some more. This is not sending memos, or only doing town halls with senior leaders. This is about cascading messages throughout the structure of the organization and about empowering midlevel leaders with messages and actions to communicate; it is also about listening to staff via anonymous email inboxes or through the change network or direct communication at the trenches. Receiving feedback is imperative for the success of any organizational change.
- *Action 7* is to manage resistance. Managing resistance is one of the most feared actions by leaders. There is a perception among some leaders that it is uncomfortable or difficult. While this can be true, it is unavoidable, and when done properly, it is not as bad as some leaders may think. Schmieder and Gartenberg (7) describe a few reasons for resistance to change (Table 11.2). These include the following.
  - *Not understanding the* why. This is rooted in a lack of articulation about the reasons for change in the communications with staff.
  - *Not understanding the change itself*. This can be related to the lack of clarity about the specifics of the change. It is necessary to communicate to staff what is specifically changing but also what is not changing.
  - *Not understanding how the change will affect them*. This could result from the lack of adapting the messages to individual needs of the staff or from not equipping midlevel management with the tools to adapt the message to the lower levels in the organization.

Table 11.2 Reasons why people resist change

Not understanding the *why* (7)
Not understanding the change (7)
Not understanding the impact of the change in them (7)
Perception that their skills are obsolete (7)
Perception that rewards are not commensurate with the effort (7)
Culture of mistrust (7)
Perception that the change is a temporary fad
Perception that the organization is not entitled to their efforts

  - *Fear that their skills will be obsolete*. Individuals understand that change begets the need to update skills. Some individuals, especially those long-term staff that might be used to a particular way of doing the work, might be threatened by the need to upgrade.
  - *Perceptions that the rewards are not commensurate with the challenge*. This is related to the perception that individuals have that all change efforts are going to be fruitless in terms of their improvement in working conditions.
  - *A culture of mistrust*. If in the past, senior leadership has not been transparent with the staff, the organization runs the risk of resistance to change due to not wanting to assume risks.
  - *A perception that the change is a temporary fad*. This could be related to a prior experience of failed changes.
  - *An attitude that the organization is not entitled to their extra effort*. This happens if the engagement of the staff is low.

Managing Resistance

Based on the models reviewed in this chapter, there are two actions which are proposed to manage resistance. The first is to suppress value judgment about the employees. Judgment about the character of the people resisting is not helpful. The second is to listen to the concerns of the staff. This is an opportunity to debunk misconceptions and to obtain ideas that leaders may not have thought about before. Allow for collaboration in developing new processes. The staff is closest to the work, and in many cases, they can improve how they do their work. Communicate and demonstrate consequences. This does not mean disciplining or firing staff that are not changing; rather, it means considering how they will feel working in an organization that is moving forward while they are stuck in the past. Showing small wins can convert the biggest dissenters. Most people want to be associated with success, and it is important to demonstrate when changes go well. Create a unifying vision about the future. This unifying vision is about the hope that things can be better.

Auditing and Reinforcing the Change

Audit behaviors that can obstruct the change and treat the new as current. This not only helps people that are resisting but also creates a sense of accomplishment, since the language and nomenclature of the organization are associated with the new state. It is necessary for leaders to offer recognition for the accomplishments staff are achieving as they go through the change. This needs to happen along the way by establishing milestones and not waiting until the whole change is complete to offer recognition. Finally, leaders must collect feedback from staff. They are closest to the work, and in the majority of cases, they have great ideas

本书版权归John Wiley & Sons Inc.所有

on how to improve. This will give them a protagonist role in the change, increasing the probability of buy-in and decreasing the probability of change fatigue.

SUMMARY

Managing change is not about processes or better technology or better ways of doing things. It is about supporting people in the psychological function of going through change. Change can be painful, and reacting temporarily in a negative way to it is not deserving of judgment. Most people go to work every day wanting to do the right thing, but in times of change, it can be difficult to do. The role of the leader is to remove obstacles, to coach and train individuals, and to trust their expertise as a useful catalyst of change. If leaders try for compliance, they will get partial compliance and permanent resistance. On the other hand, if leaders try for buy-in, at the very least they will get compliance.

KEY POINTS

- Change management is about supporting individuals as they experience the psychological challenges that accompany change.
- The field of change management is different from project management. Change management deals with the people side of change.
- Resistance is a natural response to change. It is crucial to manage it in a positive and proactive way.
- Transparency and multidirectional communication are keys for success in change management.

GLOSSARY

ADKAR (Acronym for Awareness, Desire, Knowledge, Ability, and Reinforcement.) A sequential model created by Jeff Hiatt that explains what is required for individuals and groups to succeed during change.

Change The process of becoming something different.

Kotter model An eight-step model to facilitate and implement change in organizations, proposed by John Kotter.

Resistance to change Behaviors exhibited by individuals or groups which demonstrate a rejection or at least hesitation about the proposed change(s). These behaviors can be willful or just a natural reaction to the perceived threat of a change.

WIIFM An acronym that means What's In It For Me. It represents a principle of change management in which special attention must be given to communicating aspects of the change as they apply to individual employees, focusing on the employee's perspective.

REFERENCES

1. **Caldwell SD**. 2017. Organizational change, p 1073–1976. *In* Rogelberg SG (ed), *The SAGE Encyclopedia of Industrial and Organizational Psychology*, 2nd ed, vol 3. SAGE Publications Inc, Thousand Oaks, CA.

2. **Lewin K.** 1947. *Field Theory in Social Science*. Harper & Row, New York, NY.

3. **Hiatt JM**, **Creasy TJ**. 2012. *Change Management: The People Side of Change*, 2nd ed. Prosci Learning Center Publications, Loveland, CO.

4. **Hiatt JM**. 2006. *ADKAR: A Model for Change in Business, Government and Our Community*. Prosci Research, Fort Collins, CO.

5. **Kotter JP**. 1996. *Leading Change*. Harvard Business School Press, Boston, MA.

6. **Kotter JP** (ed). 2018. *8 Steps to Accelerate Change in Your Organization*. Kotter Inc. https://www.kotterinc.com/8-steps-e-book-download/. Accessed 20 July 2023.

7. **Schmieder RA**, **Gartenberg DL**. 2017. Organizational change, resistance to, p 1076–1078. *In* Rogelberg SG (ed), *The SAGE Encyclopedia of Industrial and Organizational Psychology*, 2nd ed, vol 3. SAGE Publications Inc, Thousand Oaks, CA.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 11.1 Case Study

This case study is based on a group of laboratories that had several community accession centers in a region.

THE PROBLEM THAT DROVE THE CHANGE

The leadership of the organization received a significant number of complaints from patients who had to wait to have their clinical specimens collected, sometimes for over an hour, even if they had an appointment.

THE ACTIONS TAKEN

Several actions were taken in response to the complaints.

- The leadership of the organization decided to set a target for wait times at the collection sites.
- A group of experts in process improvement from within the laboratory was assigned to identify issues with the processes and to improve them.
- A change in the flow of patients was implemented. There was one person welcoming patients and collecting information, a group of staff members entered the patient data in the system, and a group of phlebotomists collected the patients' samples according to the priority order assigned.

RESULTS

After many months of implementation and adjustments, the locations were able to improve the patient wait times significantly. Also, the number of patient complaints was reduced. In many cases, some sites consistently exceeded the targets. This also improved employee morale and the general atmosphere of the locations.

However, this was not done overnight. It took certain adjustments in the process, and there was a lot of resistance from many members of the staff. Below are some of the manifestations of resistance exhibited by the staff and actions that were taken to manage them by the leadership team. The reader is invited to assess whether these actions were appropriate.

Manifestation of resistance	Action(s)
Staff complained that with the new process they had to walk more during the day, which made them more tired.	A step counter was assigned to each staff member before and after the change in the process at sites which had not transitioned yet. The purpose was to demonstrate that there was no significant increase in steps.
Employees questioned the need for a wait times target. One comment was "We are the only lab in this city; patients have no choice but to wait."	Sessions on customer service were delivered to staff. Several conversations on exploring empathy and patient-centric care were led by the leadership team with the support of the change management team.
The EKG process was not working well with the changes.	Staff members were invited to provide ideas on how to improve the process. A successful pilot was conducted, and as a result, most sites adapted to the new process.
Staff members complained that they had to explain the new process to patients several times a day. They were tired of it.	Building on the concept of empathy, the idea proposed by the change management team was that although they had to say things several times, it was only one time for each patient. Leadership acknowledged the difficulties and offered support during the transition.
Some staff members distributed an unofficial form to the patients and encouraged them to complain about the new process.	Leadership took swift action. In collaboration with HR, coaching was provided where needed. Also, where discipline was needed, it was issued.

本书版权归John Wiley & Sons Inc.所有

III

Personnel Management

(SECTION EDITOR: **Melinda D. Poulter**)

12 **Employee Selection**
Anthony S. Kurec

13 **Performance Appraisals and Competency Assessment**
Lynne S. Garcia

14 **Staffing and Scheduling**
Patti Medvescek

15 **Teams, Team Process, and Team Building**
James W. Bishop, Dow Scott, Stephanie Maynard-Patrick, and Ji-Yeon Seok

16 **Labor Relations**
Emily A. Snavely and Lynne S. Garcia

17 **Workplace Drug Testing and the Clinical Laboratory**
Lindsay A. L. Bazydlo

本书版权归John Wiley & Sons Inc.所有

本书版权归John Wiley & Sons Inc.所有

12

Employee Selection

Anthony S. Kurec

Introduction
Diversity, Equity, and Inclusion (DEI) in the Workplace
Criteria-Based Job Descriptions (CBJD)
Basic CBJD Requirements • Criteria-Based Job Description Review • Minimal Personnel Requirements
Search Process
Search Committee • Advertising
Interview Process
Screening Résumés • Interview Formats • Interview Questions • Interview "Do's and Don'ts"
Hiring Process
Candidate Selection • Orientation and Onboarding • Documentation
Separation from Service
Retention • Losing an Employee • Progressive Discipline • Termination
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES

OBJECTIVES

To recognize and understand the differences in cultural, generational, and other diverse groups in the workplace and their impact on the hiring process
To discuss the desirable elements of a criteria-based job description
To describe how to establish a search committee
To list, then critique, various approaches to the interview process
To give examples of appropriate and inappropriate interview questions
To describe the ideal orientation process
To address potentially useful retention techniques available to laboratory leaders
To describe the steps of progressive discipline

Good training will not fix a bad selection.

Diana Mass

If you don't have a good attitude, we don't want you, no matter how skilled you are. We can change skill levels through training. We can't change attitude.

Herb Kelleher, Founder, Southwest Airlines

Personnel management styles have evolved over the years based on the current environmental, governmental, and cultural trends. The function of the clinical laboratory is to ensure good patient care by providing quality laboratory services accurately, efficiently, and cost-effectively. The demands placed on laboratory professionals to expand their knowledge base, their skills, and their productivity have forced laboratory leaders to invest more in the hiring, maintenance, and development of their staff (1). This has also refocused efforts to actively support diversity, equity, and inclusion (DEI) opportunities for individuals who may have been underrepresented in the laboratory profession. Recognizing and eliminating intentional or unintentional discriminatory biases based on differences in race, ethnicity, gender, transgender, disability, and other characteristics may offer employees proper access to certain positions that will allow for advancement opportunities. Studies have shown that those workplaces that have put forth the effort in developing DEI practices have greater productivity and profitability and fewer recruitment problems (2). When hiring, greater consideration must be placed on recognizing an individual's ability and attitude over any other characteristic in order to develop a diverse workforce that benefits patients, the laboratory, and the organization.

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch12.

本书版权归John Wiley & Sons Inc.所有

The need for an adequate number of trained laboratory personnel has been and continues to be a concern. Over the past several decades, many training programs have closed, with a concomitant reduction in the number of graduates. Through a concerted effort by numerous professional organizations and participating laboratories, this issue has been actively addressed, though not fully resolved, even though vacancy rates that were as high as 20% a few years ago have decreased to less than 12% in most areas of the laboratory (3). For many of the upcoming new graduates, data gathering, laboratory analysis, test result monitoring, and information dispersal will be their main focus. Further, as molecular-based testing increases, it is clear that laboratory leaders will need the best and brightest to meet the challenges of these advanced technologies. To attract and keep key people, a collective effort between employee and employer will be required so that both reap the benefits of this relationship.

Due to a large number of Baby Boomers (born between 1946 and 1964; see Table 12.1) entering retirement, in conjunction with the modest number of graduating students, predictions by the Bureau of Labor Statistics show a 7% increase from 2019 to 2029 in the number of laboratory personnel needed (4, 5). The estimated 73 million aging Boomers not only are leaving the workforce, but will place a greater demand on the healthcare system, ultimately requiring the service of a greater number of healthcare employees (6, 7). In addition to the loss of staff due to the increased number of retirements, the complications resulting from the COVID-19 (SARS-CoV-2 virus disease) pandemic further eroded staffing numbers (8). For some laboratories, testing volumes decreased when elective procedures at hospitals were stopped and the staff was furloughed or had reduced hours. Other staff members were victims of COVID-19 or were COVID-19 exposed and had to isolate. Those laboratories that had to develop and perform COVID-19 testing with a demand for rapid turnaround times had to add staff, increase hours of operation, or readjust staffing assignments to accommodate the increase in testing. These pressures placed on the remaining staff resulted in excessive stress and staff burnout, thus ultimately affecting staff retention. During this time, national travel restrictions impacted the recruiting efforts of new staff. Cross-training of existing staff increased, as well as the challenges of training non-medical laboratory scientists (those with only degrees in biology), further challenging laboratory operations. Workplace safety for some laboratories became a problem when social distancing within the laboratory was necessary and staffing per shift had to be reduced, while phlebotomists who had concerns about interacting with the public left for other non-healthcare-related jobs (8).

During this COVID era, healthcare professionals, as with many other industries, were also faced with what was termed the "Great Resignation." In 2021, over 47 million Americans quit or changed their jobs, with almost 2.8 million healthcare workers resigning in the last 6 months of 2021 alone. A second situation also emerged known as "Quiet" quitting, a phenomenon that has been perpetuated through social media. This refers to workers who consciously do no more than they are minimally required to. This disengagement is estimated to affect about half of the U.S. workforce, particularly Gen Zs and younger millennials (<35 years old). Laboratory leaders have had to learn how to be more creative in recruiting and retaining staff and in developing strategic plans when challenging situations, such as the pandemic, present themselves (9–11).

Diversity, Equity, and Inclusion (DEI) in the Workplace

With today's globalized world and the confluence of diversity within the workforce, laboratory leaders need to be better communicators with staff in a multi-diverse environment. While the goal for laboratory leaders is to take charge in identifying and selecting those individuals who can best accomplish the complex tasks within the laboratory, it is important to note that those who ignore DEI practices often have difficulties in keeping staff (12). Today's healthcare practices are complex and require a well-educated and trained workforce who understand and communicate appropriately with a diverse population of patients and other healthcare workers. This diversity is based not only on race or ethnicity, but also on language, culture, age, gender, gender fluidity, religion, social class, and disabilities. In a similar fashion, mental, cognitive, learning, and sensory disabilities may also require careful consideration. As a laboratory leader, it is important to do the right thing and avoid mistakes when you can. Laboratory leaders need to understand and acknowledge these differences so that they are neither overstated nor trivialized. There needs to be a greater sensitivity to practicing diversity, equity, and inclusion (DEI) when hiring and managing employees, and greater awareness that ethical and legal issues may be raised when DEI is ignored.

Establishing policies that ensure DEI in staffing is important. While diversity addresses the physical presence of different groups of individuals, equity promotes policies, procedures, and resources that actively support diversity. Inclusion serves as the goal to ensure an outcome that creates an environment of involvement where all individuals have access to equal, effective, and meaningful participation within the organization (13). Currently, there are greater than 300,000 medical laboratory professionals in the United States, with an average age of 43 years. Approximately two-thirds are female and one-third are male. Almost 60% are Caucasian, 15% Hispanic/Latinx, 12% Black/African-American, 12% Asian, and <1% Native

本书版权归John Wiley & Sons Inc.所有

American. Spanish, French, Chinese, Vietnamese, and Hindi are the most frequently spoken languages besides English. And finally, 9% of laboratorians have identified themselves as LGBTQ+ (14). Laboratory leaders must be aware of and sensitive to this diverse makeup and the opportunities that it potentially can bring to the table, and thus to the need to recognize, develop, and support staff by employing a well-thought-out succession plan that will best identify and mentor staff.

While many of these diverse segments have been well defined, individuals with disabilities should also be carefully considered in the hiring and managing of staff. The CDC has estimated that approximately 61 million Americans have a mental or physical disability. The overarching term of "disability" includes any physical, cognitive, mental health, learning, hearing, vision, or communication impairment that is not unique to any race, gender, nationality, or any other group (15). Accurate criteria-based job descriptions are critical in defining the essential functions of the job without discrimination against any individual. Accommodations for some physical disabilities can often be made and should be considered. For example, a hearing-impaired person might require a sound amplification device on a laboratory phone, or a person of short stature may require an adjustable chair. In a similar fashion, those individuals with cognitive, learning, and/or sensory challenges may also require additional support to perform job functions. Neurodiversity is a relatively new term that reflects variations in how people experience and interact with their world. This includes a large number of common conditions such as anxiety disorders, attention-deficit/hyperactivity issues, autism spectrum disorder, eating disorders, and others (16). The National Institutes of Health has estimated that approximately 20% of all U.S. adults have some sort of mental health issue (17). One or more members of staff may have such a condition, and thus it is necessary for laboratory leaders to be aware of any unintentional or unconscious bias when hiring and managing staff, and to recognize that all individuals must be treated equally with dignity and respect (17, 18).

Among the most common cultural attitudes that have influenced the management of the workforce are those reflected in generational differences. Five commonly recognized work-aged-based groups have traditionally been identified loosely based on the birth year, with characteristics that appear to be common among that group (19–22). Listed in Table 12.1 are some of those characteristics (23). In a recent study (24), the authors noted that there is little empirical evidence that supports generational differences, but rather that these differences are a result of hyped stereotyping. Further, they posit that it is the lifelong

Table 12.1 Generational-related differences[a]

Age group (birth year)	No.	Characteristics
Traditionalists (1934–1945)	<1 million	Work first and work hard, loyal to an employer, save money, prefer a clear chain of command, exercise if forced to, community service (e.g., Masonic Lodge, Knights of Columbus, Kiwanis Club, VFW), quality first, must vote, motivated by money and responsibility, conservative. Communication: handwritten notes, not like email. Influences: radio babies, World War II, Korean War
Boomers (1946–1964)	71.6 million	Workaholics, care about what others think, work hard, play hard, spend hard, are team players, minimally tech-savvy, have democratic views, optimistic, humane values. Communication: phone, face-to-face meetings, some email. Influences: TV generation, Cold War, civil rights, Sexual Revolution, Vietnam
Generation X (1965–1980)	65.2 million	Driven somewhat by money but also by principle; value fun, efficient, informal workplace, may not openly disagree with management even though they have issues, are doers though not always perfect, play hard, worry about money, exercise is a duty, the "Gap" generation, look for bonuses and stock options; flexible with both technology and in-person interactions; value independence, like to have priorities set, will use metrics to meet goals. Communication: whatever is most efficient. Influences: Watergate, latchkey kids, Y2K, increased divorce rates
Generation Y or Millennials (1981–2000)	73 million	State-of-the-art, individual first, live with parents, community service is punishment, Abercrombie's generation, want time off, portable skills, company loyalty is minimal, most are independent and not team-oriented, self-employment is best, not afraid to give feedback, achievement-oriented, impatient for professional growth. Communication: instant messaging (IMs), texts, email. Influences: AIDS, 9/11 terrorist attacks, Great Recession, "everybody is a winner"
Gen Z, iGen, or Centennials (2001–2012)	68 million	Considered to be true "digital natives" in that their smartphones are essential tools and the main form of communication. Focused on personalities and less on race, gender, or other diverse groups. High student debts shape their choices for work and compensation. Ambitious, can multitask better than previous generations, sometimes cynical. Communication: IMs, texts, social media. Influences: mass shootings, gender fluidity, extensive social media presence, climate change, racial/ethnic diversity

[a]See references 19–21.

本书版权归John Wiley & Sons Inc.所有

experiences that one accumulates over time that define the individual and not necessarily the generation the person was born in. While some traits may be unique to an age group, there is overlap, and thus, age or generational characteristics are not an absolute in describing each group, nor should they be considered as criteria in the hiring process; however, they may provide some insight into actions and conversations relevant to that individual.

Modern technologies have enhanced opportunities to identify a wider pool of potential applicants, thus requiring a process that allows for the selection of the best-qualified individual in a fair and consistent manner. Lost opportunities for both employer and employee may occur if differences, as described above, are not appreciated or are misunderstood. Laboratory leaders may inadvertently miss an opportunity that would otherwise capture an excellent employee by not taking the time to learn about and understand some of the fundamental differences encountered when interviewing candidates that present as "different." This does not mean that laboratory leaders should "profile" individuals based on specific characteristics and place them in "boxes," but they should raise their level of sensitivity in recognizing the uniqueness of those individuals. Hiring decisions must be based on education, skills, experience, and personal traits that meet the needs of the job. Stereotyping candidates based on "they are not like me" syndrome can lead to a stifled and cloned workforce that may be less progressive in their thinking and actions, i.e., "that's the way we've always done it" (1). Judging a potential employee without considering other personal characteristics (in addition to technical and/or knowledge-based skills) and their ability to succeed can result in not selecting the right person for the job. While it is important to have a diverse workforce, there also need to be ways for underrepresented individuals to have access and inclusion in higher-level positions, thus actively promoting DEI practices. Ensuring the inclusion of new employees by immediately and actively welcoming them to participate in laboratory activities will result in promoting a stronger DEI program (25).

Laboratory leaders need to think differently about how to recruit and manage a diverse workforce by establishing a strategic plan that can be implemented to achieve equity and inclusion. In the 1960s, the Civil Rights Act was passed to ensure equal opportunities for all Americans; however, implementing relevant opportunities has been mixed. In order to have a meaningful DEI program, an awareness of individuals and their uniqueness within the multi-diverse workplace must be clearly articulated. By breaking down silos and enhancing communication, the groundwork for strategies can then be developed to aid in achieving goals. Equity is key to providing opportunities for all to meet their full potential and to be able to recognize that not all opportunities will work for everyone. Laboratory leaders need to dig deep to effectively cultivate undiscovered talents that uniquely reflect groups within the multi-diverse workforce. The differences and similarities within and among groups lead to defining expectations or metrics that can be used in setting goals. Laboratory leaders then must make conscious efforts to provide a sense of involvement (inclusion) by actively promoting participation by and for all employees. Peter Drucker said, "Culture eats strategy for breakfast" (26). This means that any plans an organization may have, while perhaps essential to the future growth and development of a laboratory, will not be fully effective if leadership fails to actively embrace DEI and understand cultural differences and similarities. In part, it is important to teach that a disability is a type of social identity, not just a medical condition. Discrimination and social prejudice based on the belief that disabled people are "less than" is known as *ableism*. Laboratory leaders must avoid stereotyping groups of individuals and assuming they lack certain abilities or skills (15). Some best practices to help establish a DEI program are noted in Table 12.2.

Table 12.2 DEI best practices[a]

- Laboratory leadership must be involved, committed, and lead the charge
- Establish DEI metrics (employee demographics, hiring outcomes, retention rates, etc.)
- Review salary data to see if any disparities
- Involve a number of staff to ensure fair and diverse representation
- Encourage open and honest dialogue, constant communication
- Perform exit interviews and stay interviews; they can serve as effective policy-developing tools

[a] See reference 61.

Criteria-Based Job Descriptions (CBJD)

Basic CBJD Requirements

A criteria-based job description offers a comprehensive format that addresses the expectations of both the employer and the employee (27, 28). An example and typical format for a criteria-based job description might include the information presented in Table 12.3 (27). It should be based on state and federal legal regulations regarding laboratory personnel (i.e., CLIA), the need for certification and/or licensure, educational essentials, critical tasks related to the job, and work environment needs. Within the job description, each job duty may be classified as a basic core task, an advanced technical skill, supervisory responsibility, or an educational obligation, in addition to noting the essential functions required to successfully complete those tasks and the frequency of their performance (29, 30).

Job titles should be consistent throughout the laboratory, with consideration of local and national nomenclature that

本书版权归John Wiley & Sons Inc.所有

Table 12.3 Criteria-based job description example

Job Title: Medical Laboratory Scientist - Level I
Purpose: Collect and analyze body fluids used in the diagnosis, treatment, management, and prevention of disease using state-of-the-art biomedical instrumentation and other methods providing critical information to a patient's healthcare provider.

Criteria		Information to include
Minimum requirements	Education	Academic degrees and/or specific coursework that provides the skills/training
	Certification	Certification is generally voluntary, though most laboratories may require it. Certified individuals have passed an accredited examination indicating that they possess at least entry-level knowledge of the job.
	Licensure	State or federal laws may mandate qualifications and some states require licensure of laboratory personnel. Often includes a specific scope of practice
	Experience	The minimum number of years of experience that meets the needs and level of the position How much on-the-job training will be needed
Duties	General duties	May include safety, confidentiality, compliance, HIPAA, customer service, and/or time and attendance responsibilities. Any administrative duties, quality assurance, supplies/materials/equipment management, etc. Basic computer skills, Microsoft Office, etc.
	Technical duties	Technical functions specific to the job title and the frequency of performance
	Teaching	Does this position require teaching of staff, students, or the public? Will the incumbent have to provide on-the-job training of staff?
	Research	Does this job require research activities such as research and development of new techniques, instrumentation, etc.?
	Unique skills, abilities, or other required knowledge	Special individual skills such as speaking a second language, writing skills, communication or presentation skills
	Work environment	Does the position involve travel (nursing home, satellite labs, home draws, etc.)? Working conditions: biohazards, chemical hazards, radiation, etc.
	Essential functions	What physical and mental demands are required, i.e., amount of time standing, sitting, walking, manual dexterity, vision/color vision, lifting/moving, stress, etc.
Professional development	Expectations/opportunities	What is expected in professional growth with this position? Are there any regulatory requirements for professional development and continuing education that have to be met?
Organizational	Table of organization Direct reports	How does this position fit into the departmental or institutional table of organization? To whom or to which position(s) does the incumbent report? Which positions report to the incumbent?

may be used in describing them. Inconsistency in title usage can confuse both laboratory and hospital staff. The U.S. Department of Labor provides detailed descriptions of occupations and related information by searching for specific job titles through its O*NET website (31). Only minimum, essential qualifications should be listed in the job description, to avoid the inadvertent elimination of an otherwise good candidate and an action that may be viewed as discriminatory. Because a new employee is an "unknown," documentation by way of the criteria-based job description may play an important role in retaining a new employee or if any potential disciplinary issues may arise. Hiring a qualified candidate starts with establishing the right criteria needed to meet the goals of the laboratory and the organization. While education, specific technical skills, and experience are critical, equally important is identifying appropriate personality traits and attitudes that are conducive to being a team player. These traits are subjective and are not easily quantifiable or tangible. Asking candidates for examples where they have demonstrated such traits and documenting them as part of the interview process can offer a glimpse into a candidate's personality; these traits, however, should be confirmed when talking with the candidate's references.

Criteria-Based Job Description Review

With changing and enhanced technology, safety concerns, and regulatory mandates, a needs assessment should be completed when a vacancy is first encountered. This type of documentation can serve as evidence for the need to maintain the position in place and can help convince senior leadership of this need. Benchmarking is a standard laboratory practice, and thus workload statistics, estimated revenue, a cost-benefit analysis, and any other relevant projections should be provided in support of why the position should be refilled. Consider the following questions: "Is this position still relevant?" "Can existing staff absorb these duties?" "Could a part-time person handle these duties?" "Should these tests be outsourced?" "Have this position and its job responsibilities changed?" Advances in

本书版权归John Wiley & Sons Inc.所有

technology often dictate how a test may be performed or even if the test is still relevant. Laboratory tests that were once performed manually required a greater number of full-time equivalents (FTEs) to accommodate the time-consuming assay process. Many tests are now automated, thus improving accuracy and efficiency, and may not require as many FTEs as originally allocated. Several examples of obsolete tests are the lupus erythematosus cell test (or LE prep) and the bleeding time. Justification for the position can shift from the need to perform time-consuming tests to better understand new technologies, implementing them, and reporting test results quickly and accurately. An honest needs assessment in determining if a vacancy needs to be refilled also speaks to the due diligence required in meeting the fiduciary responsibility of a laboratory leader.

As part of the needs assessment, the criteria-based job description should be reviewed for accuracy to ensure that the job duties listed are based on established policies and procedures (criteria) and are still relevant to laboratory operations. This is a critical step because this document serves as an informal "contract" between the employee and management by setting the job expectations for both employee and employer. Care in constructing a criteria-based job description is important for many reasons, as discussed here, but also can carry some legal weight in cases of employee-employer disputes. Criteria-based job descriptions need to be balanced in detail, for if too brief in definition, they may invite applicants who are not qualified, thus unnecessarily adding to recruitment efforts and costs. Conversely, requirements that are too detailed or restrictive may discourage good candidates from submitting their applications. Whether creating a new or revamping an existing criteria-based job description, consider recent changes to the laboratory environment. Financial constraints often force some laboratories to downsize, combine sections into core facilities, merge multiple hospital laboratories into one, and/or outsource a greater number of laboratory tests, thus changing staff responsibilities to accommodate the laboratory's needs. Major technology upgrades in automation have eliminated many time-consuming manual methods, again directly impacting staffing needs. Conversely, growing technologies such as molecular/genetic testing have created new positions. These changes have impacted the addition or elimination of certain duties, hence the need for careful review and justification as to whether refilling the position is appropriate.

Minimal Personnel Requirements

For the laboratory, minimum personnel requirements are addressed in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). These requirements have identified the key laboratory titles and responsibilities which are described in detail elsewhere (29–31). In addition, a number of states mandate licensure of laboratory personnel, potentially adding another level of personnel requirements. In states without licensure, many laboratories require certification through a professional agency such as the American Society for Clinical Pathology's Board of Certification (ASCP-BOC). Individuals who are certified have demonstrated that they have met the minimum educational requirements and possess the appropriate level of knowledge in their specified area of laboratory science (32, 33).

Specific job duties must also be identified to ensure that the incumbents understand what they are to do. Overly detailed descriptions can lock a laboratory leader into an unwanted position when staffing needs have to be flexible. An employee claiming, "That's not in my job description" is something a laboratory leader does not want to hear. Yet, incorporating the general statement "and other duties as assigned" is often discouraged by human resource professionals due to its vagueness and can lead to employee/employer disputes. For example, assigning nontechnical duties (such as washing glassware, mopping floors, or trash removal) to a medical laboratory scientist (MLS) as punishment for poor job performance may be considered working out-of-title and possibly discriminatory. Yet, there may be times when such participation is needed, especially in smaller laboratories. Further, whereas some tasks such as cleaning refrigerators, freezers, or incubators may not be a regular responsibility for more senior staff, it would behoove them to be responsible enough to oversee such functions from a quality management point of view. Similarly, informing secretaries that their job now includes performing phlebotomies can also lead to formal complaints. If disgruntled employees tender their resignation as a result of this type of practice, legal action could be taken. Therefore, a balance in detail and flexibility must be considered when revamping or creating a new criteria-based job description. Other attributes to be noted include to whom this position reports, levels of responsibility beyond laboratory testing (administrative, educational, research, duties, etc.), and accountability, thus letting incumbents know where they stand in the decision-making process. It is useful to list job relationships (Table of Organization) so the incumbent clearly knows the laboratory's hierarchy and what other internal/external relationships are involved. It may be appropriate to add a disclaimer indicating that the job description will be periodically reviewed and that duties and responsibilities may change as needed. Affirmative Action/Equal Opportunity statements are sometimes included, reflecting the laboratory's commitment to DEI. At the end of the hiring process, it is wise to document the job description with signatures and dates for the newly hired employee and the laboratory leader to sign. With each new hire, the experience gained by a laboratory

本书版权归John Wiley & Sons Inc.所有

leader in an employee selection process is cumulative and can be applied to future hiring practices.

Search Process

Search Committee

Depending on the level of the position to be filled, a full search committee may not be necessary. For entry-level positions, the interview process should involve no fewer than two individuals, most often the supervisor and manager. To ensure a fair evaluation of résumés, it is best, and legally safer, to have at least a second person involved as part of the selection process, to ensure fairness in which résumés to seriously consider. When hiring for specialty positions or at the supervisory level or above, it is advisable to assemble a formal search committee consisting of an appropriate mix of individuals. While the committee should remain small (five to seven people), the mix should reflect the diversity of the department and the expertise needed to determine the applicant's qualifications. A pathologist, a supervisor from another section, a nonsupervisory staff person, and/or an individual from another department that may have dealings with the incumbent can offer input or subtle nuances of the job that might otherwise be missed. This also creates a sense of contributing to the workforce (inclusion) and offers training opportunities for individuals who want to learn interviewing skills. As noted, an appropriate committee mix of gender, gender fluidity, ethnicity, race, and/or age should be considered to minimize any perception of bias in selecting the candidate (34). This again serves as an opportunity to actively demonstrate inclusion and is consistent with affirmative action and equal opportunity guidelines. This also protects the employer from situations where the selection process might be questioned as reflecting intentional or unintentional bias. If a committee is not formed, ensure that at least two individuals review résumés, interview candidates, and provide some level of input to the final decision, in order to minimize any appearance of preferential treatment. It is important to have a written hiring process policy that includes guidance in the prevention of discrimination in the workplace and appropriate hiring practices.

This may also be an appropriate time to consider DEI training for the committee. Critical to the success of this type of training is how the training is approached. Some studies have suggested that mandatory DEI training does not meet the intent it is supposed to. While it is generally embraced by those who have been traditionally considered marginalized (i.e., racial or gender biased), mandatory DEI training can face resistance from non-marginalized or majority-group employees due to a sense of "being forced" to participate (35). DEI training needs to be individualized to meet the laboratory's needs or to resolve specific issues, yet should never be just a "check-box exercise." In addition to DEI practices, there are other important federal laws to review to ensure fair and equitable laboratory management. Table 12.4 lists a few Equal Opportunity Employment regulations that were designed to prevent discriminatory hiring practices based on gender, age, race, religion, sexual orientation, or other non-work-related characteristics. Lack of attention to these regulations can result in severe penalties for those who violate them (34).

Advertising

An employer must make a reasonable effort to ensure that there are equal opportunities for all qualified candidates to become aware of the open position. Posting a vacancy on social media sites such as Indeed, LinkedIn, Glassdoor, ZipRecruiter, or Monster generally provides a wide range of access to potential candidates from a large, diverse population. Also, consider advertising on websites that are affiliated with underrepresented populations (36); examples include diversity.com and workplacediversity.com.

When documentation of U.S. citizenship, an H-1 visa, or a green card would be required for employment, this should be noted clearly. The advertisement should be concise and contain the job title, the essential job requirements, the minimum educational requirements, and any applicable licensure or certification requirements. Most employers include a diversity attestation statement and may include a special notation to encourage underrepresented individuals to apply. When advertising a job vacancy, avoid words or phrases that may be vague or subjective or appear discriminatory. Clichés and jargon can be confusing or misinterpreted. Table 12.5 offers a few suggested words or phrases that should be avoided in developing a job posting (37). Poorly worded job postings can inadvertently discriminate against otherwise good candidates. Additional basic items that should be included are the required work hours/schedule, any travel requirements, and union status, if appropriate. Posting of salaries, unless required, should be deferred until the final interview discussion, as it might deter good candidates from applying or encourage less qualified candidates. Most employers will (or should) have predetermined salary ranges based on responsibilities and experience for each job title, thus minimizing concerns of pay inequities (38).

Consider also where to advertise. Seeking both internal and external candidates provides the largest pool from which to select and should be used whenever possible. However, there may be times when union contracts, financial limitations, or institutional practices prevent such a wide search. Internal postings can offer some advantages, such as an opportunity for internal advancement, and serve as an incentive for existing staff. This also reduces the learning curve, recruitment time, and related costs (no travel/hotel expenses, minimal advertising expenses, and

本书版权归John Wiley & Sons Inc.所有

Table 12.4 Equal opportunity employment regulations

Regulation	Purpose
Civil Rights Act of 1964 (amended 1972 and 1991)	Prohibits discrimination based on color, race, religion, gender, or national origin; established Equal Employment Opportunity Commission (EEOC). Executive Order 11246 of 1965 created affirmative action programs requiring employers to establish plans to address racial disparities in hiring and promotion, in conjunction with the Civil Rights Act.
Age Discrimination in Employment Act of 1967	Prohibits employment discrimination based on age; protects people who are 40 or older
Equal Pay Act of 1963	Prohibits discrimination in compensation based on gender when performing the same duties
Equal Employment Opportunity Act of 1972	Gives the EEOC authority to process antidiscrimination court cases
Vocational Rehabilitation Act of 1973	Supports grants to states for vocational rehabilitation services, to include assistance in employment and independent living, by prohibiting discrimination in employment based on physical or mental disability
The Pregnancy Discrimination Act of 1978 (Amended Title VII)	Prevents discrimination against a woman because of pregnancy, childbirth, or related medical conditions on the basis of a disability
Guidelines on Sexual Harassment (1980)	Defines sexual harassment and establishes standards in preventing discriminatory practices
Worker Adjustment and Retraining Notification Act of 1988 (WARN Act)	Mitigates mass layoffs without notification in a facility with more than 100 employees and requires 60 days advance notification to give workers and their families transition time to prepare for lost employment by seeking other opportunities, including retraining in order to compete in the job market
Title I of the Americans with Disabilities Act of 1990	Prevents discrimination on the basis of a disability
Family and Medical Leave Act of 1993 (FMLA)	Job protection for up to 12 weeks of unpaid leave a year for eligible employees who need to care for a newborn or placement of a child for adoption/foster care, for an immediate family member with a serious health condition, or for the employee due to a serious medical situation
The Genetic Information Nondiscrimination Act of 2008	Illegal to discriminate against employees or applicants because of genetic information, including that from family members who might have a genetic disease/disorder
Fair Chance to Compete for Jobs Act of 2019	Prohibits federal contractors and agencies from requesting criminal history records before a conditional job offer is made

Table 12.5 Words and phrases to avoid in job postings

Word or phrase	Discriminates against:	Suggested alternative
Young and energetic Youthful Supplement your retirement Great opportunity for student Mature person needed	Age (implies that only individuals of a certain age will be considered)	XYZ institution is an equal opportunity employer.
Great opportunity for a career woman Opportunity for a mom to re-enter the workforce Seeking a male (female) candidate	Gender	
Clean-shaven	Religion (certain religions require men to wear facial hair)	
Carry or lift	Disability	Use if the job requires routine moving of reagent or waste disposal equipment, etc., that may weigh up to 50 pounds
Stand, sit, bend		Use only if the position requires the ability to remain in a standing position for long periods of time (e.g., microscope users; phlebotomists)
Vision, color vision	Disability	Use if the position requires the ability to accurately visualize cells, colors, or other images using a microscope, or to discern color changes
Driver's license		Should not be asked unless it is needed for the job (e.g., courier)
Special preference for veterans Veterans need not apply	Veteran status	References to military status need not be mentioned.
Must be at least 5′ 10″ Weight must be appropriate to height Must be fit Mental status	Physical/mental attributes	References to height, weight, or other physical or mental attributes should be avoided.

本书版权归John Wiley & Sons Inc.所有

possibly a salary less than that commanded by an external candidate). Conversely, the disadvantages of hiring from within are the lost opportunity to bring in "new blood," loss of potential innovation and leadership skills, creation of a "vacancy chain reaction" (the sequential moving of one person to another position resulting in a new vacancy to be filled), and the internal competition among coworkers for the position. Also, filling a more senior position with someone who was once an equal-level coworker with others can create some challenges, thus requiring an honest discussion with both the new boss and staff about this new relationship and how all parties can best work together.

Some laboratories may need to conduct a national search for senior-level positions or unique positions such as cytogeneticist, or when the local pool of applicants is sparse. The cost can be thousands of dollars and the process can take considerable time to complete. Advertising nationally can be expensive and can add months to the search time. Website advertising is generally less costly and widely accessible. In addition to advertising vacancies, a laboratory leader can conduct his or her own search for a specific job title to actively seek out individuals who have already posted their résumés. A final alternative is to use a job search service that finds appropriate candidates. A fixed fee or a certain percentage of the incumbent's annual salary (about 15 to 20%) is usually charged for this service.

Interview Process

Screening Résumés

Depending on the number of résumés received, screening for the appropriate qualifications can be very time-consuming and should not be taken lightly. While there is no one great technique for screening résumés, a common one is to divide them into three groups. Group 1 consists of those individuals who have outstanding qualifications, meet the criteria outlined in the hiring policy, and are strong candidates for the job. Group 2 includes those who meet the minimum qualifications but may have limited experience or some other minor concerns, for example, someone with a number of years of experience in chemistry who is applying for a blood bank vacancy (newly hired blood bank techs generally require many months of training before they can work on their own). This person may not be the top candidate but should not be discarded based on this alone. If none of the group 1 candidates is viable, those in group 2 move up the list. Group 3 includes those individuals who do not meet one or more of the qualifications. In reviewing résumés, consider the applicant's use of spelling, grammar, and syntax. If a candidate does not take the time to carefully review and submit a well-written résumé, it may suggest a lazy, irresponsible, or otherwise less-than-acceptable candidate. Consider the following when reviewing résumés:

Informal writing, inappropriate use of abbreviations, colloquialisms, and buzzwords: For example, the use of abbreviations without spelling them out can cause a reviewer to be confused or misinterpret the meaning.

Handwritten or photocopied résumés: This shows that the candidate really does not care about this job and can also cause confusion if not readable.

Appearance: The résumé should be professional looking, on quality stock white paper, and not too lengthy or too short. Note: résumés are generally short (two pages or less) and generally focused on the position to be filled, while a curriculum vitae is a complete work history and is used in academic environments. Inconsistent use of font size or font type throughout the résumé can be distracting or misread or can take too long to read, especially if a script font is used.

Colored paper, embossed emblems or watermarks, perfumed paper, candidate's picture: While these contributions may stand out to a reviewer, they do not speak to the candidate's qualifications and add little to the selection process. Perfumed paper especially may not be appreciated by those with sensitivities, and pictures may unfairly influence a reviewer's decision.

Minimum qualifications: Accepting a candidate for an interview who does not meet all the advertised minimum qualifications, even if he or she has other impressive attributes, could be subject to legal concerns regarding inappropriate hiring practices. If no candidate becomes available based on the advertised criteria, the position may have to be re-evaluated and reposted, advertising on a broader basis.

Too much information: Mention of personal facts, such as marital status, children, political activities, hobbies, etc., may inadvertently prejudice the reviewer and may reflect a lack of judgment in confidentiality. Information related to the candidate's last job (why they were let go, e.g., "had a bad boss," "supervisor was prejudiced," "coworkers did not like me," etc.) may be a warning sign of an individual who refuses to accept responsibilities.

Discriminatory practice: Be cautious in prejudging candidates based on the unique spelling of their name, foreign or ethnic derivation, revealed physical or mental issues, or gender-based differences. The departmental hiring policy and procedure should address such issues.

Inconsistencies in work history, education, or other time-relevant events: While inconsistencies in a person's work history may become the deciding factor in not

本书版权归John Wiley & Sons Inc.所有

accepting the candidate, they should not be the sole reason for initial disqualification. Acceptable circumstances might include military service, illness, or a spouse's job transfer. Allow the candidate to explain during the interview.

A poorly organized résumé that requires a reviewer to spend time searching for key points should signal a concern that speaks to that individual's lack of real interest in the position, disorganization, or laziness in wanting to put their best foot forward. This becomes particularly important when many résumés are received.

Interview Formats

Once several viable candidates are identified, decide which interview format will be used. A structured, one-on-one interview is the most common format and can offer a more intimate approach to identifying the candidate's qualities. In some instances, several interviewers may work together in evaluating a single candidate. Prepared questions serve as a guide and allow for the interview to stay focused, though should not necessarily be used as a script, which would minimize opportunities to ask follow-up questions. Prewritten questions ensure that appropriate questions are asked that focus more on the candidate's qualifications, and can help steer the interviewer away from asking inappropriate ones that may be considered discriminatory. The fact that the person is being interviewed indicates that he or she meets minimum qualifications, and thus questions should be constructed to gain a greater sense of the candidate. Open-ended questions usually require more than one-word answers, thus providing candidates time to discuss their skills, their strengths, what they bring to the position, and what their future goals might be. These questions also serve as documentation of the interview, ensuring the interview was conducted in a fair and appropriate manner. Unstructured interviews (no prepared questions) may be more free-flowing but can lead to a confused and rambling interview which may result in difficulty with documenting responses.

In some instances, a group interview may be used, especially when a large number of qualified candidates are under consideration. Several candidates can be interviewed at the same time by two or more individuals taking turns in asking the preassigned questions. The advantages are that more staff can be involved in the process at one time, the questions and answers are heard by all, inconsistent or troubling answers by a candidate can be easily corroborated, time commitments and scheduling difficulties are minimized, and the candidate can observe interactions among potential new coworkers. Having multiple interviewers also minimizes the potential or perceived biases of a single interviewer. The main disadvantage of a group interview is that it can be overwhelming to the candidates. The candidate should be notified of the agenda and interview process prior to the meeting.

If there are many applicants, prescreening candidates by phone can be helpful. More recently, online video conferencing interviews have gained popularity, especially with candidates who would have to travel for a face-to-face interview. Such screening can be done with minimum scheduling problems and potentially allows for more than one interviewer to participate. It also eliminates the cost and time to bring a candidate to the interview, and is an option when the candidate cannot travel due to unique circumstances (such as a pandemic), yet still offers the opportunity to observe nonverbal communication (body language).

As a follow-up to candidates not selected, an interview rejection letter or email should be sent that politely and professionally thanks them for their time and interest. It might also mention that they have an impressive background and encourage them to continue to pursue their professional endeavors. This puts a polite and professional face on the process and allows the candidate to move on. For those candidates who were well qualified but not selected, note that their information will be kept on file for future consideration if a position becomes available that may be a better fit. Offering specific reasons as to why they were not selected should be avoided, as they may be construed as discriminatory (i.e., based on candidate's age, gender, national origin, race, marital status, disability, etc.).

Interview Questions

When interviewing, use clear and concise language, avoiding jargon, idioms, or slang words or phrases. For those candidates whose English is a second language, fluency or accents may be an issue; thus, if it is unclear as to what has been said, the interviewer should paraphrase and repeat back to ensure understanding. Pay attention to verbal and nonverbal cues (body language). Eye contact, handshaking or other gestures, personal space, and speaking volume are viewed differently in various cultures. Be aware that these differences are not necessarily meant to be rude or disrespectful but may be a cultural basis of how an individual responds. Also, do not assume that culturally different persons know everything about their own culture or are typical of their group; rather, it is important to recognize the individual, his or her qualifications, and what is actually said.

Different interview question formats can be used during the interview process. It is useful to quantify responses to each question by using a scale of 1 to 5. By quantifying responses, a fair and measurable evaluation of each

本书版权归John Wiley & Sons Inc.所有

candidate will be easier to make. In general, five types of interview questions can be constructed (25, 30, 32):

1. Leading questions are easy and result in obvious answers. These are not very informative and should be avoided. Several examples might be: "Are you a hard worker?"; "What are your weaknesses?"; or "Why do you want to work here?" Most candidates will have preemptive answers to these types of questions and tell you what you want to hear.
2. Direct questions often receive short or simple answers such as yes or no. While a limited amount of information is obtained, these questions can help gain some information or lead to a follow-up question. An example is "Have you had hands-on training in performing phlebotomies?"
3. Open-ended questions require the interviewee to provide a more complex answer. A significant amount of information can be obtained from these types of questions. Answers to these questions allow the interviewer to observe the candidate's manner, style, affect, ability to think on their feet, and level of articulation. The candidate must think about the response and provide an acceptable answer. Examples of open-ended questions might be: "Tell me about your relationship with your previous supervisor"; "Tell me something about yourself that is not on your résumé"; "How do you deal with conflict?"; or "What might you do in support of DEI initiatives?"
4. Probing questions frequently allow for follow-up questions. Once a candidate answers a question, a specific point can be probed with another question that elicits more information. An example is a query about the level of training or education a candidate professes to have, such as "How does your training apply to the job offered?"; "How does this position fit into your long-term goals?"; "What will your previous employer tell me that you need to improve on?"; "What will your previous employer tell me you excel at?" Questions of "how they resolved" a particular problem sets them up for an easy answer in that the answer is in the question, so they know their reply must include, "I resolved the problem by. . ." A better use of the interview time, and a more informative probing question, would be to ask about a time that they did *not* resolve an issue. These questions require the candidate to formulate an answer and will most likely not result in a prepared answer.
5. Hypothetical questions can be useful and are often asked toward the end of the interview as an opportunity to further determine how a candidate thinks on their feet. Problem-solving questions require the candidate to utilize their training and/or experience to properly answer the question, such as, "If you had to reduce your budget by 20%, how would you go about it?" This allows an interviewee the opportunity to demonstrate knowledge of budgeting, staffing, finances, instrumentation, and other related operational or personnel managing skills. Questions unrelated to job duties that may be construed as "psychological" or "stress-situation" questions are not appropriate and can set a tone of defensiveness. An example would be, "What is the worst lab error you have ever made?"

Be aware of hackneyed responses from a candidate, such as "I am a team player/deadline driven/a quick learner/a hard worker/always reliable." These claims may be an enhancement of their true abilities and are often difficult to confirm. The main goal of the interview process and the kinds of questions asked is not to grill candidates or invade their privacy, but to determine their measurable accomplishments and to gain a sense of their ability to do the job and their flexibility to meet the changing needs of the job. Be aware that expecting a candidate to fit into the existing laboratory culture may reflect an unconscious bias that has set a norm that may or may not be obtainable, or even reasonable, for some people representing marginalized groups. The expectation of them changing to "fit in" may actually violate efforts to implement and sustain DEI (13).

Interview "Do's and Don'ts"

Before the interview, review the criteria-based job description, the candidate's résumé, and the list of prepared questions. Table 12.6 offers some interviewing tips. Bring the candidate to a quiet and private area. Put the

Table 12.6 Ten interview tips

1. Review the applicant's résumé before the meeting.
2. Be prepared with questions, and allow for adequate time to discuss any questions the applicant has.
3. Schedule meeting in an office or other quiet place.
4. Make the candidate feel welcome with one or two general, non-interview questions, e.g., weather, travel, etc.
5. If you are the first interviewer, explain the agenda for the candidate regarding who else will be interviewing, tour of the lab, or any other action that will occur as part of the interview process.
6. Avoid asking stress questions, controversial questions (religion, politics, etc.), or illegal questions.
7. The interviewer should talk 25% of the time; the interviewee talks 75%.
8. It is best to avoid making any promise(s) to a candidate.
9. Be prepared to answer questions about the hospital/laboratory. While candidates ares trying to sell themselves to you, it is important for you to sell the laboratory to them.
10. If you do not know the answer to a question, don't guess.

本书版权归John Wiley & Sons Inc.所有

candidate at ease by asking a question not related to the job—about the weather, the commute to the interview, or some other light topic. This will help to establish rapport and put the candidate at ease. Avoid any personal comments about the candidate's dress, haircut, body art, or any other personal features that are not relevant to performing the job. Questions about marital status, age, nationality, family situation, sexual orientation, religion, or political or social affiliations are not acceptable. It is appropriate to ask about gaps in work experience, about a lack of job progression as noted in the résumé, or about the candidate's time and attendance history. Questions regarding arrest records and criminal convictions have come under scrutiny in the past few years. It may be viewed as discrimination if an individual with a past criminal history who possesses the appropriate requirements of the job is immediately dismissed as a potential candidate. Currently, there are laws in 37 states and over 150 cities and counties that require employers to remove criminal history questions on initial application forms ("Ban The Box"). More recently, the Fair Chance to Compete for Jobs Act of 2019 (see Table 12.4) was passed by Congress, extending these policies to government positions. Each candidate must be judged based on the nature of the crime, whether it was job-related, and/or how long ago it occurred (39, 40).

Laboratory leaders must also be familiar with the Americans with Disabilities Act (Table 12.4) and avoid any questions that may appear to be discriminatory if a candidate has a physical or mental concern. You may ask the candidate if there are any tasks listed in the job description that he or she could not do, but you cannot discriminate based on the perception of a candidate's inability to accomplish job-related requirements. Those individuals who appear to have a disability may be able to accomplish assigned tasks with the use of technological aids or workspace modifications.

Hiring Process

Candidate Selection

Candidates interviewed should be evaluated based on their qualifications, their responses to the interview questions, and their attitude as to how they present themselves. It's been said that skills and experience are two legs of a three-legged stool, with the third leg being attitude. One study found that almost one-half of new hires were fired or disciplined within the first 18 months. Of these cases, 89% resulted from attitude problems and not necessarily incompetence (41). High performers tend to answer questions focused on what they did (using the phrase "I did. . ."), as opposed to low performers, who will refer to past accomplishments in vague terms, often in the third person, and be more focused on future events.

To fairly evaluate each of the candidates, a fixed ranking system (1 to 5) can be useful in assisting the search committee in assessing each candidate objectively. Before any job offer is made, ask for at least three references and ensure that each reference is checked. References that do not include an immediate supervisor or some other higher-level individual should be discussed with the candidate. Given our litigious society, most employers are very discreet in what information they release (generally, only confirmation of employment, dates employed, and job title) unless the candidate has given his or her permission for further information to be revealed. A reference for an exceptional employee will offer high accolades with little or no prompting. While you may learn much from what the reference says about the candidate, listen carefully to what *is not said*.

Doing background checks and obtaining financial credit reports have become common practices as a part of the final steps of the hiring process. One study found that the cost to recruit and train a replacement for a bad hire was up to $50,000 (42). This research is necessary to ensure the safety of patients and staff as well as protecting the employer. Greater security in screening employees for past indiscretions, especially since September 11, 2001, can be a critical deciding factor in placing the individual in a position that involves the management of people, finances, chemical/biological materials, or patient information. Such investigations may include a review of driving records, credit reports (access may be restricted in some states), felonies, drug/alcohol problems, and sex offender status. Failing to perform an official background check on the final candidate despite the expense and length of time it takes to complete may cause legal repercussions for the employer if a new hire repeats a crime while in their employ. Current background check laws prohibit employers from asking about past criminal history until they issue a formal offer. However, certain employment areas, including healthcare, are generally excluded. Asking about criminal records on the application form before a firm offer is made is prohibited in some states (39, 40).

An employer can request a pre-employment check after receiving permission from the candidate. Note that individuals denied a position after what was perceived as an illegal background check have brought lawsuits against potential employers. Some employers have embraced internet social media sites as additional resources in scrutinizing candidates. Since all job applicants tend to put their best foot forward during an interview, visiting these sites may reveal a perspective of the candidate that otherwise would have been missed. In a study by Penn State, 70% of employers that were surveyed used social media to view public posts by potential candidates, and 48% use it

本书版权归John Wiley & Sons Inc.所有

to check on existing employees (43, 44). Finding profiles that reflect self-absorption, negative/harsh opinions, drug/alcohol use, or other unprofessional activity may contribute to making a final decision in hiring, especially when several candidates are under consideration. The use of the internet for this purpose has raised privacy issues as well as legal concerns that may arise, especially if a candidate's protected class (race, gender, religion, age, etc.) is violated (44, 45). If social media is used as part of the screening process, it is best to consult with Human Resources or legal counsel to develop a policy that includes which websites will be used, what information may be collected, and the number of sites and time spent in the review process. In general, the Human Resources department will obtain other legal documents that include an employee identification number (EIN), W-4 from the IRS, and any documents regarding eligibility to work in the United States.

Orientation and Onboarding

Once a candidate is hired, proper orientation and onboarding must be prompt. Orientation is the initial introduction to the key aspects of the laboratory and laboratory staff. This usually occurs on day 1 and may last several days when necessary. Onboarding is a series of events that can take place over several weeks to several months depending on the position and related responsibilities. Orientation and onboarding policies should be developed to ensure that these programs are organized and provide the needed guidance in minimizing confusion and frustration for the new employee while creating an environment that allows the new employee to feel like part of the team. This structured format offers consistency in the hiring process and protects the employer from any problems that may arise when an employee says, "I was never told that." Table 12.7 lists some key points that should be covered during orientation.

The more a new employee knows about operations, expectations, laboratory safety, and the general atmosphere of the workplace, the better their assimilation into the team, thus further promoting inclusion. A prepared orientation checklist that is signed by the new employee and the trainer can document what has been covered and will prevent any misunderstandings about responsibilities. Making the new employee a priority by both leadership and coworkers sets a tone for acceptance and being part of the team. The orientation training should include the immediate supervisor and other experienced staff who can provide useful information on day-to-day operations, a review of policies and procedures, a copy of the employee handbook, and a discussion of nontechnical basics such as the locations of the cafeteria, coffee shops, restrooms, lockers, etc. (see Table 12.7).

In healthcare settings, patient and laboratory safety are key topics as part of orientation. In light of the COVID-19 pandemic, a greater focus has been placed on mandating vaccinations as a condition of employment. The CDC recommends that healthcare workers receive certain vaccinations (46) (Table 12.8). Enforcement of these mandates can vary from state to state, in addition to certain exceptions to these requirements. Employers must seek reasonable accommodations for those employees who refuse to receive certain vaccinations for legitimate causes such as medical reasons, pregnancy, religious-based beliefs, a union agreement, or other undue hardship (47).

In conjunction with orientation, the process of onboarding is an essential part of promoting employee retention. Onboarding intends to make a new employee feel accepted. This should begin by assigning a mentor who can help in this process. This provides a connection between the employee, coworkers, and management and creates a feeling of engagement from day 1 of employment. Understanding the roles and rules within an organization is critical to a successful hire. Assigning meaningful work with appropriate supervisory involvement provides a clear path forward for both employer and employee. A new employee will start off knowing there is an established line of communication and accountability. Onboarding is a process of playing the long game in supporting and developing a new employee who is recognized for their contributions and assumes a positive future with the laboratory.

Documentation

It is important to document the search, hiring, and orientation processes. This ensures consistency, addresses any legal requirements, and demonstrates fairness in hiring practices. Examples of the kinds of documentation to be retained include a copy of the criteria-based job description, résumés of those seriously considered for the position (retaining résumés on file for any future vacancies may also come in handy), a copy of the advertisement(s) and where it was posted, a sample of interview questions, offer (or rejection) letter(s), and responses from references. Hiring records must be retained for a minimum of 1 year, in addition to an additional year if the employee was involuntarily terminated (48). In practice, most employers keep these documents for considerably longer; for some employee records, 3 to 30 years may be required. Consult with your human resources professional for guidance in determining how long certain records should be retained. This documentation protects the employer if there are questions about hiring practices. However, be aware that retention of records longer than required can be discoverable during a legal inquiry and can become a liability issue. In today's litigious society, every laboratory leader must be cautious by ensuring that documentation

本书版权归John Wiley & Sons Inc.所有

Table 12.7 Employee orientation program checklist

Item	Date
Table of organization	
Historical overview of the organization	
Laboratory tour and meet the staff	
Mission and vision statements (departmental, hospital, or other)	
Operations	
Share/review job description	
Laboratory safety, fire safety, universal precautions	
Hospital security, ID cards	
Confidentiality (Health Insurance Portability and Accountability Act, HIPAA)	
Laboratory compliance plan	
Quality assurance, quality control, total quality management, and continuous quality improvement programs	
Laboratory information system training	
Purchasing requests: supplies, equipment, etc.	
Performance evaluation, competence training, continuing education	
Promotion/raises	
Laboratory handbook of policies	
Right to know	
Material Safety Data Sheets (MSDS)	
Sexual harassment policy	
Miscellaneous issues	
Educational opportunities (personal development, continuing education)	
Customer service, telephone etiquette	
Personal phone calls, cell phones, iPods, etc.	
Internet use	
Dress code/appearance/grooming	
Time and attendance expectations	
Vacation, sick leave, overtime accruals, and requests for time off (Family Medical Leave Act, FMLA)	
Lunch/break area	
Lavatory location(s)	
Lockers	
Payday	
Parking	
Smoking policy	
Required vaccinations	
Employee Signature & Date:	
Supervisor Signature & Date:	

is complete and follows established institutional human resource guidelines to best protect the laboratory leader and the institution from accusations of perceived unfair hiring practices or situations of wrongful employment separation.

Separation from Service

Retention

A major goal of any laboratory leader is to ensure that they make the best attempt in hiring what they hope will be a long-term and productive employee. Table 12.9 outlines some retention options that may be considered. In some cases, voluntary resignation may be averted through better channels of communication or through other adjustments as already noted. In a study by the College of American Pathologists (CAP), the median 3-year average for laboratory employee turnover rate was 16.2%, with general staff at 11.1% and phlebotomists at the high end at 24.9% (49).

Table 12.8 CDC vaccine recommendations[a]

COVID-19
Hepatitis B
Influenza
MMR (measles, mumps, rubella)
Varicella (chickenpox)
TDP (tetanus, diphtheria, pertussis)
Meningococcal

[a] From reference 46. Reasons for employer accommodation include medical reasons, pregnancy, religious-based beliefs, union agreement, or undue hardship.

本书版权归John Wiley & Sons Inc.所有

Table 12.9 Suggested retention options

Practice	Option
Good hiring practices	Hire the right people Have realistic goals and expectations Perform a thorough job search Check references
Communication	Bidirectional communication Have frequent meetings Manage by walking around
Training	Develop an orientation process Adequately train staff and supervisors in job duties, interpersonal skills, communication, etc. Encourage teamwork Encourage continuing education
Recognition	Find people doing something right Praise people often Foster a positive work environment Encourage ideas, positive attitudes, and innovative thinking Allow more employee participation in decision making Celebrate successes
Work environment	Maintain a safe work environment Provide adequate tools to do the job Establish a workable infrastructure
Survey/feedback	Measure outcomes as part of quality assurance Monitor attitude Be aware of workplace stress inducers Know employee problems and how they relate to the workplace Communicate

Unexpected, voluntary separation from service will sometimes occur; however, in most cases, it should not be a surprise if laboratory leaders are fully engaged with their employees.

One technique that has proven to be useful in engaging with staff is the "stay interview." These periodic interviews can offer good information as to why an employee wants to stay or what may make them want to leave (50). Frank and frequent conversations will work toward establishing a sense of being heard and offer opportunities for de-escalating the potential mass exodus of unhappy employees. Table 12.10 offers a few suggestions on what to discuss in a stay interview. By showing support for employees, assigning them to areas that are most meaningful for them, showing them that they are respected and valued, ensuring job safety, and promoting a feeling of loyalty and commitment to those employees, to coworkers, and to patient care can create a long-lasting relationship.

Table 12.10 Some examples of stay interview questions[a]

- Tell me a couple of reasons why this is a great place for you to work.
- How is your job going and what can I do to make your job better?
- What makes you want to come to work each day?
- What is your dream job?
- What motivates you?
- What is the best thing about your job? The worst?
- If you were in charge, what would you change?
- What can I do to better recognize you?
- What additional skills do you bring to the table that are not currently being used?
- What additional areas of the lab would you like to learn more about?
- What might make you want to leave?

[a] See also reference 50.

Losing an Employee

The cost of losing an employee, hiring a replacement, and then training the new one can be very expensive. According to a Gallup poll, the average cost of replacing an employee can range from one-half to two times the employee's annual salary (51). These costs include the loss of productivity, potential loss of customers, and staff morale concerns, in addition to significant costs related to advertising, the interview process, orientation/onboarding, remaining employees' overtime (to cover the shortage), training time, human resources and payroll processing, and/or other recruitment or start-up expenses. In addition, the payout costs of any unused vacation time, prorated bonuses, and hiring temporary help can also add to these expenses. Losing an experienced employee can be particularly costly in terms of lost institutional knowledge and experience. Thus, when an employee asks for a pay raise, the laboratory leader must consider replacement costs versus the dollar amount of the raise, in addition to any DEI issues or inequities that must be addressed. No laboratory leader wants to be held hostage to an employee's salary demands, but a fair and equitable review should follow to ensure that

本书版权归John Wiley & Sons Inc.所有

an increase for one employee is not significantly greater than that of others who perform the same duties, have similar education/experience, and have workplace longevity. The employee should be advised that initial salaries are set based on the education and experience requirements of the position and that any future raises would be justified if the employee were to take on additional duties or responsibilities. Further, any adjustments would be limited to available funding and institutional guidelines. When additional funding is just not available, an honest and straightforward discussion with the employee is warranted, perhaps with the promise of reconsidering the situation at a later date.

A good laboratory leader will also attempt to be proactive by recognizing excellent employees by rewarding them in a timely fashion before such a situation occurs. However, laboratory leaders must also work within their budgets. If negotiations have broken down, consider alternatives to monetary compensation by offering "soft currency" options such as putting them in charge of a committee or task force, offering official recognition for a job well done ("Laboratorian of the Month"), a change in title (without a pay increase), or additional training opportunities, or offering flexible hours or additional time off. Splitting a 40-hour full-time line into two 20-hour lines may satisfy two people. This latter approach may be particularly enticing for those who want to stay involved but can only work part-time. Recognition of an employee's accomplishments and showing respect is key to their retention but also can be used in support when future funding becomes available for a pay increase. Yet, there will be employees who are unwilling to work with the laboratory leader, especially during a period of financial concerns, and ultimately might be a better fit elsewhere. Frequently, money issues can turn an otherwise excellent employee into a disgruntled one, creating an unproductive, disloyal, and angry employee who is no longer a team player and instigating an unpleasant and potentially hostile work environment for coworkers.

People leave their jobs for many reasons. Some are personal (marriage, spousal job change, pregnancy, illness, etc.), while others leave due to work-related issues (burnout, dislike of boss/coworkers, desire for more money, poor work conditions, poor work hours, no recognition) and still others may be seeking professional development opportunities (returning to school, joining the military, promotional opportunity). Whatever the reason, good leaders will listen to their employees and establish avenues of bidirectional communication. Employers need to be sensitive to employee needs, stress levels, any multi-diverse differences, and the general morale of the work environment. Offering pay raises, enhanced benefits, promotions, and/or other costly opportunities may be beyond control at the laboratory level. However, acknowledgment by a supervisor of a job well done shows a level of sensitivity that is appreciated by staff. Recognizing what can and cannot be done and sharing that with employees often demonstrates to them that you, as the representative of the employer, are not indifferent to their concerns and serve as an advocate for them (Table 12.9).

Progressive Discipline

Even when a laboratory leader has completed due diligence in hiring an employee, there may be situations when that employee will require corrective action. The process of progressive discipline gives the employee ample opportunity to address the employer's concerns and make necessary adjustments. Conversely, it also provides the employer with an opportunity to review and clarify any unreasonable policies and/or expectations that set the employee up for failure. Criteria-based job descriptions and departmental policies that have not been updated may be part of the problem. Progressive discipline is not always restricted to just job performance, but may be necessary when an employee demonstrates verbal micro-aggressions such as inappropriate rudeness, bullying, or unconscious racist, homophobic, or sexist comments. More physically overt actions (macro-aggressions) will require immediate attention.

A written policy outlining the steps of progressive discipline should be developed and include language that also addresses egregious events that may require skipping certain steps of progressive discipline and going directly to immediate dismissal (52). How much counseling is required depends on the severity of the problem and the employee's history and status. If discussions between the supervisor and the employee do not result in the desired outcome, a more aggressive approach is required, thus progressing to the next step. This progressive process will end either with a mutually acceptable resolution or with the employee's termination, which may be voluntary or involuntary. This process is rigidly adhered to for many institutions, especially those facilities that have union representation. While there is some flexibility in the private sector, the rules, if ignored or unfairly deployed, can lead to legal action by the dismissed employee. The main steps in progressive discipline counseling are:

Verbal counseling. This is the initial communication between the employer and employee specifically addressing the concerns. This first recognition of the problem is documented and generally maintained as an internal document. Depending on the degree of severity and the length of time between the undesired actions, several episodes of verbal counseling may be appropriate. Counseling should take place as soon as possible after the incident to avoid any additional complications of the issue. For most employees, no

本书版权归John Wiley & Sons Inc.所有

further action is needed once the concerns are pointed out to them. Though handled internally, it is wise to give Human Resources a heads-up that a problem exists and that verbal counseling will begin.

Written counseling. If there is no performance improvement after several verbal counseling attempts, additional counseling occurs with the preparation of a formal, written memorandum. The memorandum must be specific, noting the circumstances, previous verbal counseling episodes, times, dates, individuals involved, and proposed corrective actions. This often involves an official investigation with extensive documentation that becomes part of the employee's personnel record.

Penalty stage. If unacceptable employee actions continue after the written counseling, penalties may be imposed, such as a fine, leave without pay, a decrease in pay, or demotion. Documentation of the additional improprieties is put in a written memorandum to the employee and added to the personnel file. When discipline reaches this level, the relationship between employee and employer can be strained, creating additional problems and spiraling into an unpleasant work environment. Poor attitudes, a loss of productivity, and inefficiencies may be evident. Coworkers may also be directly or indirectly affected when working in a tense environment. Termination may be the only option at this point.

Termination. When no other options or corrective actions are apparent, termination of employment is the final stage. Regardless of the stage of discipline, guidance from the Human Resources department is recommended to ensure that all legal procedures are followed, thus minimizing any basis for legal recourse by the dismissed employee. Whether going through the stages of progressive discipline or termination, having a trusted witness as part of the discussion is wise. Documentation at each step is essential. A useful format to assist in collecting information that describes the circumstances leading up to the dismissal is the "Five W's + H": What happened? When did it happen? Where did it happen? Why did it happen? Who was involved? How can it be fixed?

A good laboratory leader creates the kind of work environment that offers opportunities for employees to be most productive and efficient in their jobs. The goal is to maximize the use of available resources, whether human, financial, physical, or other, to ensure that the workforce is proud of what they do and will remain loyal to the laboratory. Employees who know what is expected from them and what support they can expect from their employer, work in a clean and safe environment, and have the right materials and tools to do the job are satisfied employees who will be loyal and provide long-term service to the institution. Whenever possible, performing an exit interview to get feedback from the departing employee may generate useful information that can be acted on and implemented to prevent future issues. Questions that revolve around the work environment, such as their best/worst experience, what improvements might be made, specific problems, and what additional support would have made a difference, may uncover an unknown problem.

Termination

Circumstances that may lead to the involuntary termination of an employee WITHOUT cause may be due to budgetary constraints forcing work staff reductions. This type of termination is not necessarily a reflection of the employee's performance or job ability, but a bottom-line, financial decision. Facilities with more than 100 full-time employees or who work a total of 4,000 hours per week may fall under the WARN Act (see Table 12.4), which requires 60 days of advance notification of any mass layoff. Some states have exceptions implemented based on unforeseeable circumstances or governmental action, as seen during the COVID-19 pandemic, which had a major impact on the workforce (52).

Involuntary termination WITH cause is almost always a result of poor job performance or a disrupting presence of the employee. When an employee appears to be not a good fit for either the employer or employee, it is incumbent for the employer to make every reasonable attempt to correct a problem and help the employee to understand where the lack of communication exists or identify other situations that have contributed to the poor performance. It is wise to consult with Human Resources or the legal office at an early stage to ensure termination is approached legally and fairly.

Involuntary termination with cause must be free from any discriminatory actions based on race, age, gender, disability, or other protected class (53). Except for contract employees, an employee-employer relationship is generally based on "at-will" employment, where either party can terminate the relationship at any time. An employer cannot terminate an employee if it violates any antidiscrimination laws or if there is a violation of public policy, as in the case of a whistleblower who reports a healthcare fraud. Telling how and when terminations will occur may be viewed as an implied contract, known as a "just cause" promise. With several exceptions, most states have some form of at-will employment rules (53, 54). Over the years, a number of laws and court cases have addressed wrongful termination issues; thus, an employer must use care in proceeding to terminate an employee, especially one with a physical or mental impairment who qualifies under the Americans with Disabilities Act (ADA) (55). Under FMLA (the Family and Medical Leave Act), employees who work

本书版权归John Wiley & Sons Inc.所有

for a "covered" employer (i.e., 50 or more employees with 20 or more workweeks; Federal, State, and local employers; public and private school employers) and are qualified (i.e., have worked for that employer for 12 months with 1,250 work hours) may take up to 12 weeks (or 26 weeks for a military service member) of unpaid job-protected leave each year. Dismissing such an employee based on unscheduled work absences can be legally contested and the laboratory leaders can be held accountable (56).

For some employees with personal issues that have become problematic in the workplace, referral to the Employee Assistance Program (EAP) for appropriate counseling may be considered (57). The top EAP concerns are stress, relationships, and child behavior issues, yet only about 10% of employees use EAP resources that might help in resolving issues (58). The immediate termination of an employee without careful review of the situation can lead to lengthy and costly legal outcomes. A long-term employee who is terminated, especially one who has had previous satisfactory reviews, has received raises, is part of a protected class, or has not received written warnings, may have cause to file legal action against the employer. However, employees who have threatened or abused patients or staff, compromised patient data, intentionally falsified their credentials, purposefully damaged equipment, or committed a felony can generally be terminated immediately even if they fall within one of the protected categories.

While there is no perfect time or day that is best to terminate an employee, Friday afternoons may allow the employee to cool off over the weekend, but may also allow them to worry or increase their agitation over the dismissal (59). Termination early in the week may be more efficient in de-escalating a problem, but may also result in a disruptive situation between the employee and coworkers if the employee is not promptly removed. Depending on the reason for the dismissal, the middle of the week may be best, thus allowing the employee to meet with human resources to answer any final questions (unemployment, health insurance, severance pay, etc.), to collect personal items or return any materials belonging to the laboratory (ID card, phone, etc.), and say good-bye to coworkers. Table 12.11 offers some suggestions for the termination meeting.

Table 12.11 Termination process

1. Have a witness with you.
2. Meet in a private area close to an exit.
3. Review the progressive discipline steps that have been taken and the key facts for the dismissal.
4. Be prepared to answer questions about unemployment, references, health insurance, vacation payout, separation package, etc.
5. Do not get into a "discussion." Deal with facts, not emotions.
6. Conduct an exit interview if appropriate.
7. The next steps: collect personal items, take back ID card and any other lab-owned equipment, terminate any computer access.
8. Arrange for an escort off the premises if appropriate.
9. Keep meeting brief, no more than 15 minutes.
10. Stay in control of the conversation, watch what you say, and DOCUMENT.

SUMMARY

As in any business, supply and demand dominate the competition for qualified candidates. The Bureau of Labor Statistics estimates that the profession will grow another 25,000+ workers between 2021 and 2031, an issue compounded by the decrease in the number of training programs, which have declined by 7% since 2000. The pandemic of 2020–2021 has placed an even greater burden on filling laboratory positions (60). Though many laboratory procedures are automated, it is anticipated that laboratorians will spend more time gathering data, analyzing, monitoring, and dispersing information to healthcare providers. Laboratory test results that took days if not weeks to report can now be done in hours, and sometimes minutes. Laboratory leaders will need the best and brightest minds to meet the challenges of these new technologies and to ensure accurate and timely dispersion of information. Attracting and keeping these key people will take a collective effort between employer and employee so that both reap the benefits of this relationship with the common goal of providing quality patient care.

KEY POINTS

- Every vacancy should prompt a reconsideration of the necessity, qualifications, and requirements for the position, any of which may have changed over time.
- Careful consideration in writing job descriptions, advertising, interviewing, and assignment of duties must include DEI practices.
- The criteria-based job description, advertising method, interview process, and selection criteria should be carefully analyzed before attempting to fill a job vacancy to ensure it is a fair and effective process to find the right candidate.
- Those responsible for these processes must be aware of local policies and legal requirements governing the selection and hiring process, as well as employee termination procedures. In some situations, laboratory leadership can be held accountable if regulations are not followed.
- Documentation of hiring, employee supervision, and separation from service is a critical management skill.
- Laboratory leaders must constantly work to retain valued employees by using a variety of techniques.

本书版权归John Wiley & Sons Inc.所有

GLOSSARY

Criteria-based job description Written delineation of the title, duties, responsibilities, and reporting relationships of a position and the requisite qualifications needed to meet these.

Diversity, equity, and inclusion (DEI) Interrelated ideas in understanding differences and perspectives within a multi-diverse workforce. Diversity can be any metric that identifies different groups or characteristics; equity provides opportunities to develop; and inclusion is the active process of involving all people irrespective of their diverse nature.

Equal Employment Opportunity Commission (EEOC) Established to prevent discrimination in the hiring and retention of employees based on non-work-related characteristics.

Exit interview Upon an employee's departure from service, this interview provides an exchange of information that can include reasons as to why the employee is leaving and any positive or negative experiences with coworkers or with other situations.

Gender fluidity Refers to a change over time that reflects an individual's sexual identity, expression, or both, that is not related to their biological origin. The acronym LGBTQIA+ is often used and stands for lesbian, gay, bisexual, transgender, queer (questioning), intersex, asexual, and (agender).

Progressive discipline Stepwise process to address deficiencies in job-related activities or attitudes.

Stay interview A regularly scheduled conversation between management and each employee to identify any current problems or potential ones. In addition, this interview helps build trust and engages the employee, letting them know that they have been heard.

Termination with cause Separation of an employee from their position that is a result of poor performance or a behavioral problem.

Termination without cause Separation of an employee from their position that is not a result of poor performance or behavioral problems.

REFERENCES

1. **Mass D.** 1999. Staff retention: a major key to management's success. *Clin Lab Manage Rev* **13**:266–274.

2. **Expert Panel, Forbes Human Resources Council.** 2021. 15 key benefits of DEI to communicate with team members. https://www.forbes.com/sites/forbeshumanresourcescouncil/2021/05/19/15-key-benefits-of-dei-to-communicate-with-team-members/?sh=4764c31f195c Accessed July 2023.

3. **Eaton KP, Levy K, Soong C, Pahwa AK, Petrilli C, Ziemba JB, Cho HJ, Alban R, Blanck JF, Parsons AS.** 2017. Evidence-based guidelines to eliminate repetitive laboratory testing. *JAMA Intern Med* **177**:1833–1839.

4. **Garcia E, Kundu I, Kelly M, Soles R.** 2019. The American Society for Clinical Pathology's 2018 vacancy survey of medical laboratories in the United States. *Am J Clin Pathol* **152**:155–168.

5. **U.S. Bureau of Labor Statistics**. 2023. *Occupational Outlook Handbook*. https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm. Accessed December 2022.

6. **Fry R.** 2020. The pace of Boomer retirements has accelerated in the past year. Pew Research Center. https://www.pewresearch.org/fact-tank/2020/11/09/the-pace-of-boomer-retirements-has-accelerated-in-the-past-year/. Accessed December 2022.

7. **United States Census Bureau**. 2019. By 2030, all Baby Boomers will be 65 or older. https://www.census.gov/library/stories/2019/12/by-2030-all-baby-boomers-will-be-age-65-or-older.html. Accessed December 2022.

8. **Garcia EC, Kundu I, Kelly MA, Guenther GA, Skillman BK.** 2021. The clinical laboratory workforce: understanding the challenges to meeting current and future needs. American Society for Clinical Pathology and Center for Health Workforce Studies, University of Washington. https://ascpcdn.s3.amazonaws.com/static/ISTP/Siemens_Clinical+Laboratory+Workforce_Brochure_042721.pdf. Accessed December 2022.

9. **Flynn J.** 2022. Stunning Great Resignation statistics [2023]: Why are Americans leaving their jobs? Zippia. https://www.zippia.com/advice/great-resignation-statistics/. Accessed December 2022.

10. **Wallask S.** February 23, 2022. Clinical laboratories suffer during the 'Great Resignation'. Dark Daily, Spicewood, TX. https://www.darkdaily.com/2022/02/23/clinical-laboratories-suffer-during-the-great-resignation/. Accessed November 2022.

11. **Harter J.** 2022. Is quiet quitting real? Gallup Workplace. https://www.gallup.com/workplace/398306/quiet-quitting-real.aspx. Accessed December 2022.

12. **Oloyede B.** 2019. Diversity and inclusion: creating a lasting environment for laboratory professionals. *Critical Values* **12**:10–11.

13. **Glassdoor Team.** 2022. Why and how organizations should create a DEI policy. https://www.glassdoor.com/blog/why-create-a-dei-policy/ Accessed July 2023.

14. **Zippia.** 2023. Medical technologist demographics and statistics in the US. https://www.zippia.com/medical-technologist-jobs/demographics/ Accessed July 2023.

15. **Pulrang A.** 2021. 3 Mistakes to avoid when including disability in your DEI program. Forbes. https://www.forbes.com/sites/andrewpulrang/2021/08/27/3-mistakes-to-avoid-when-including-disability-in-your-dei-programs/?sh=6e15fe2529aa. Accessed December 2022.

16. **Baumer N, Frueh J.** 2021. What is neurodiversity? Harvard Health Publishing. https://www.health.harvard.edu/blog/what-is-neurodiversity-202111232645. Accessed December 2022.

17. **National Alliance on Mental Illness**. 2022. Mental health by the numbers. https://nami.org/mhstats. Accessed December 2022.

18. **Lollini A.** 2018. Brain equality: legal implications of neurodiversity in a comparative perspective. *Intern Law Polit* **51**:69–133.

19. **McNamara C.** 2023. Understand generational differences: guidelines and resources. Management Library. https://managementhelp.org/interpersonal/understand-generational-differences.htm. Accessed December 2022.

20. **Parker K, Igielnik R.** 2020. On the cusp of adulthood and facing uncertain future: what we know about Gen Z so far. Pew Research Center. https://www.pewresearch.org/social-trends/2020/05/14/on-the-cusp-of-adulthood-and-facing-an-uncertain-future-what-we-know-about-gen-z-so-far-2/. Accessed December 2022.

21. **Paychex Worx**. 2019. How to manage the 5 generations of the workplace. Paychex WORX blog. https://www.paychex.com/articles/

本书版权归John Wiley & Sons Inc.所有

human-resources/how-to-manage-multiple-generations-in-the-workplace. Accessed December 2022.

22. **Purdue University Global**. 2023. Generational differences in the workplace. https://www.purdueglobal.edu/education-partnerships/generational-workforce-differences-infographic/. Accessed December 2022.

23. **Lancaster LC**, **Stillman D**. 2009. *When Generations Collide: Who They Are. Why They Clash. How To Solve the Generational Puzzle*. Harper-Collins Publishers, New York, NY.

24. **Rudolph CW**, **Rauvola RS**, **Costanza DP**, **Zacher H**. 2020. Generations and generational differences: debunking myths in organizational science and practice and paving new paths forward. *J Bus Psychol* **36**:945–967.

25. **Center for Creative Leadership**. 2022. 5 Powerful ways to take REAL action on DEI (Diversity, Equity, & Inclusion). https://www.ccl.org/articles/leading-effectively-articles/5-powerful-ways-to-take-real-action-on-dei-diversity-equity-inclusion/. Accessed August 2021.

26. **The Alternative Board**. 2020. "Culture eats strategy for breakfast"—What does it mean? https://www.thealternativeboard.com/blog/culture-eats-strategy. Accessed December 2022.

27. **Kurec AS**. 2014. Look for the perfect job by honing your interviewing skills. *Clin Leadersh Manag Rev* **28**:10–14.

28. **Hilbert T**, **Kurec AS**, **Lifshitz MS**. 2022. General concepts and administrative issues, p. 2–12 *In* McPherson RA, Pincus PA (ed), *Henry's Clinical Diagnosis and Management by Laboratory Methods*, 24th ed. Elsevier, Philadelphia, PA.

29. **Code of Federal Regulations**. 2023. Title 42, Chapter IV, Subchapter G, Part 493. Clinical Laboratory Improvement Amendments of 1988 (CLIA'88). https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5. Accessed December 2022.

30. **Passey RB**. 1998. The Clinical Laboratory Improvement Amendments (CLIA), p 17–34. *In* Snyder JR, Wilkinson DS (ed), *Management in Laboratory Medicine*, 3rd ed. Lippincott, Philadelphia, PA.

31. **U.S. Department of Labor.** 2023. O*NET OnLine. Find occupations. www.onetonline.org. Accessed December 2022.

32. **Wilkinson DS**, **Dilts TJ**. 1999. Role of medical, technical, and administrative leadership in the human resource management life cycle: a team approach to laboratory management. *Clin Lab Manage Rev* **13**:301–309.

33. **American Society for Clinical Pathology**. 2022. ASCP Board of Certification. https://www.ascp.org/content/board-of-certification. Accessed December 2022.

34. **Wilson SL**, **Snyder JR**. 1998. Interviewing and employee selection, p 195–220. *In* Snyder JR, Wilkinson DS (ed), *Management in Laboratory Medicine*, 3rd ed. Lippincott, Philadelphia, PA.

35. **Gassam Asare J.** 2022. Have we been wrongfully vilifying DEI training? Forbes.com. https://www.forbes.com/sites/janicegassam/2022/10/07/have-we-been-wrongfully-vilifying-dei-training/?sh=21cf6f413b35. Accessed December 2022.

36. **University of Michigan Human Resources**. 2011. Avoiding discrimination in job postings. Office of Institutional Equity. https://hr.umich.edu/sites/default/files/avoiding-discrimination.pdf. Accessed December 2022.

37. **Hering BB**. 2021. 5 interview questions to stop asking immediately, and what to ask instead. Business Management Daily. https://www.businessmanagementdaily.com/63049/5-interview-questions-to-stop-using-immediately-and-what-to-ask-instead/?cigx=d.ciobmd%2Csid.0%2Cstid.2546%2Cmid.3232%2Cshsh.6a716585c86d5f8b2a0446c2f02ec91b%2Cct.newsletter%2Clkid.10182&src=email.bmdcio_2546.hs-ciobmd.3232&utm_campaign=promo_cd&utm_medium=email&utm_source=hs-all. Accessed December 2022.

38. **Society for Human Resource Management (SHRM)**. 2018. How to establish salary ranges. https://www.shrm.org/resourcesandtools/tools-and-samples/how-to-guides/pages/howtoestablishsalaryranges.aspx Accessed July 2023.

39. **Harless W.** 3 August 2013. 'Ban the Box' Laws Make Criminal Pasts Off-Limits. *Wall Street Journal.* https://www.wsj.com/articles/SB10001424127887323997004578640623464096406. Accessed December 2022.

40. **Avery B**, **Lu H.** 2021. Ban the box: U. S. cities, counties, and states adopt fair hiring policies. Sept 30, 2020. National Employment Law Project (NELP). https://www.nelp.org/publication/ban-the-box-fair-chance-hiring-state-and-local-guide/. Accessed December 2022.

41. **Murphy M.** 2019. Hiring for attitude. American Management Association. https://www.amanet.org/articles/hiring-for-attitude/. Accessed December 2022.

42. **Moore D.** 2012. Bad hires: Data, costs, and avoidance tactics. HR.com. https://www.hr.com/en/app/blog/2012/06/bad-hires-data-costs-and-avoidance-tactics_h3g079qh.html. Accessed December 2022.

43. **LaJeunesse S.** 2020. Social media content matters for job candidates, researchers find. Penn State News. https://news.psu.edu/story/607015/2020/02/05/research/social-media-content-matters-job-candidates-researchers-find. Accessed December 2022.

44. **Haller B**, **Ball DR.** 2020. The legal and ethical considerations of using social media in recruiting and hiring stages of employment. Northeast Decision Science Institute 2020 Annual Conference. https://digitalcommons.molloy.edu/cgi/viewcontent.cgi?article=1078&context=bus_fac. Accessed December 2022.

45. **Foley & Lardner LLP**. 2019. To stalk or not to stalk. . .That is the question—Using social media for applicant review. *Natl Law Rev* **9**(294). https://www.natlawreview.com/article/to-stalk-or-not-to-stalk-question-using-social-media-applicant-review. Accessed December 2022.

46. **CDC**. 2022. Healthcare personnel vaccination recommendations. https://www.immunize.org/catg.d/p2017.pdf. Accessed December 2022.

47. **Smith A**, **Nagele-Piazza L**. 2022. Employers react to workers who refuse a COVID-19 vaccination. SHRM. https://www.shrm.org/resourcesandtools/legal-and-compliance/employment-law/pages/if-workers-refuse-a-covid-19-vaccination.aspx. Accessed December 2022.

48. **U.S. Equal Employment Opportunity Commission**. Record-keeping requirements. https://www.eeoc.gov/employers/recordkeeping-requirements. Accessed December 2022.

49. **Novis DA**, **Nelson S**, **Blond BJ**, **Guidi AJ**, **Talbert ML**, **Mix P**, **Perrotta PL**. 2020. Laboratory staff turnover. A College of American Pathologists Q-Probe study of 23 clinical laboratories. *Arch Pathol Lab Med* **144**:350–355.

本书版权归John Wiley & Sons Inc.所有

50. Finnegan R. 2019. How to conduct stay interviews: 5 key questions. Society for Human Resource Management (SHRM). https://www.shrm.org/resourcesandtools/hr-topics/employee-relations/pages/how-to-conduct-stay-interviews-part-2.aspx. Accessed July 2023.

51. McFeeley S, Wigert B. 2019. This fixable problem costs U.S. businesses $1 trillion. Gallup Workplace. https://www.gallup.com/workplace/247391/fixable-problem-costs-businesses-trillion.aspx. Accessed December 2022.

52. Business Management Daily. 2021. How to fire an employee the legal way: 7 termination guidelines. https://training.businessmanagementdaily.com/3322/termination-guidelines-3/?_sp=58342627-265a-4b2b-a532-5793a57669e2.1626292425270&src=bmd-freeproducts-el-terminationguidelines&_ga=2.222068504.1478372962.1626282763-2040124184.1626282763&_cbnsid=5ce69984a08bc8619198.162629242562fe92. Accessed December 2022.

53. Ramaswamy R. 2023. Understanding involuntary termination: what it is and how it works. DocPro. https://docpro.com/blog94/understanding-involuntary-termination-what-it-is-and-how-it-works. Accessed July 2023.

54. Betterteam. 2022. At-will employment. Complete guide with state information and definition. https://www.betterteam.com/at-will-employment. Accessed December 2022.

55. Upcounsel. 2021. List of disabilities covered under ADA. https://www.upcounsel.com/list-of-disabilities-covered-under-ada. Accessed July 2023.

56. U.S. Department of Labor. 2023. Family and Medical Leave Act (FMLA). https://www.dol.gov/agencies/whd/fmla. Accessed December 2022.

57. US Department of Health and Human Services. 2022. Employee Assistance Program (EAP). https://www.opm.gov/frequently-asked-questions/work-life-faq/employee-assistance-program-eap/what-is-an-employee-assistance-program-eap/. Accessed July 2023.

58. Hoyt A. 2017. Why hardly anyone uses employee assistance programs. HowStuffWorks.com. https://money.howstuffworks.com/why-hardly-anyone-uses-employee-assistance-programs.htm. Accessed December 2022.

59. Jobber Academy. 2023. How to fire someone nicely: 10 best practices. https://getjobber.com/academy/how-to-fire-someone-nicely/#:~:text=Make%20it%20clear%20that%20the,thinks%20they%20should%20be%20fired. Accessed July 2023.

60. Rohde RE. 2020. Who is doing all those COVID-19 tests? Why you should care about medical laboratory professionals. The Conversation Newsletter, Texas State University. https://theconversation.com/who-is-doing-all-those-covid-19-tests-why-you-should-care-about-medical-laboratory-professionals-151725. Accessed December 2022.

61. Shepherd L. 2022. Strategies for making DE&I more effective. SHRM, Society for Human Resource Management. https://www.shrm.org/resourcesandtools/legal-and-compliance/employment-law/pages/diversity-equity-inclusion-training-workplace.aspx. Accessed December 2022.

本书版权归John Wiley & Sons Inc.所有

13

Performance Appraisals and Competency Assessment

Lynne S. Garcia

Introduction

Performance Appraisals

Definition and History of Performance Appraisals • Purpose of Performance Appraisals • Advantages of Performance Appraisals • Trends Beyond the Traditional Performance Appraisal • Appraisal Types: Formal and Informal Appraisals • Responsibility for Developing a Performance Appraisal Program • Legal Aspects of a Performance Appraisal Program • Elements of a Meaningful Formal Performance Appraisal • Competency-Based Appraisals • Rating Methods • Other Types of Performance Appraisals • Who Should Perform the Appraisal? • Preappraisal Preparation • Steps to a Successful Performance Appraisal Interview • Benefits of Becoming a Mentor • Salary Adjustments • Strategies To Reinforce Appropriate Behaviors • Guidelines for Appraising Poor Performers • Dealing with Emotional Outbursts during Performance Appraisals • Completed Performance Appraisal Documents • Improvement Plan • Web-Based Software Products and Websites

Competency Assessment

Regulatory Foundation for Competency Assessment • Timing of Competency Assessment • Methods for Assessment of Competency • Practices • Personnel Excellence

SUMMARY

KEY POINTS

GLOSSARY

REFERENCES

APPENDIX

OBJECTIVES

To understand the purpose of performance appraisals

To discuss the historical development of performance appraisals

To understand the advantages and disadvantages of performance appraisals

To define the key elements in developing a meaningful performance appraisal

To identify methods to measure employee performance

To describe the steps that may be taken in conducting a successful appraisal interview

To list three accreditation agencies that issue competency standards

To specify three intervals or events that require competency assessment

To describe four competency assessment methods

> *As each human being is unique, we simply cannot add them together, or subtract them from one another. . .. to arrive at meaningful measurements is one of the greatest challenges of management.*
>
> Peter Drucker

The goal of this chapter is to provide you with tools that will allow you to develop and execute a successful formal performance appraisal process and competency assessment program. However, informal performance feedback appraisals are also useful for monitoring behavior modification, recognizing accomplishments, identifying stumbling blocks in achieving set goals, giving support where applicable, and fostering ongoing communication throughout the year between formal appraisals. This more informal process provides input within a mentoring system; consequently, commentary at the formal appraisal does not contain issues that have not been addressed prior to the formal performance appraisal process.

Performance Appraisals

Definition and History of Performance Appraisals

The word "appraisal" is derived from the Latin word *appratiare,* to set a price or value (1). Appraisal systems measure employee performance against accepted predetermined goals set by the employee and management personnel,

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch13.

本书版权归John Wiley & Sons Inc.所有

set future goals and objectives, and provide staff guidance on their developmental and training needs. They help managers identify both achievements and shortfalls in performance and provide a framework used to guide future improvements. Therefore, performance appraisal is the method used to evaluate or judge the ways in which an individual is functioning. A formal performance appraisal, also known as a merit review, performance evaluation, interview, or rating (2), is a planned, periodic management activity to evaluate an employee's on-the-job behavior, competency, work skill improvement, need for training, and progress toward completing goals and to make decisions regarding salary and promotion (2–4). Performance appraisals are an essential human resource function that is used to determine compensation and training, as well as career planning.

Although elements of performance review systems date back to ancient times, performance reviews began in the 19th century during the Industrial Revolution. Formal performance reviews were created and used by the military as a "merit rating" system during World War I (5). After World War II, about 60% of U.S. companies were using appraisals (by the 1960s, it was closer to 90%). Though seniority rules determined pay increases and promotions for unionized workers, generally strong merit scores were used to determine advancement opportunities. At this point in the use of appraisals, improving performance was not an important consideration. By the 1950s, performance assessment had become an integral part of personnel management. The approach was used to sort/rank workers; this was particularly effective when jobs were in short supply and applicants were numerous. By the late 1950s and early 1960s, there was a severe shortage of management talent, and organizational priorities shifted to the development of supervisors, managers, and executives. By the 1970s, with high inflation and the introduction of antidiscrimination laws, the pressure to objectively use merit-based pay was emphasized. By the early 2000s, up to two-thirds of corporate jobs were filled from outside, compared with about 10% a generation earlier. Also, by 2013, the emphasis on accountability for past performance began to fade. Jobs were becoming more complex and rapidly changed over a 12-month time frame. In an atmosphere where everyone, including employees and managers, intensely disliked performance reviews, some organizations eliminated reviews. Many feel performance appraisals do more harm than good. Rather than the traditional yearly performance evaluation, more emphasis is being placed on one-on-one discussions and ongoing feedback from supervisors during regularly scheduled check-ins. Four factors have been identified that can be used within an atmosphere of continuous changes in the workplace; these are continuous learning, monthly check-ins, building trust, and establishing connection to the work community. In summary, the emphasis has switched from looking back to looking forward, or from performance management to performance development (5, 6).

Purpose of Performance Appraisals

Some leading management authorities, such as W. Edwards Deming, renowned for his transformation of Japanese business philosophy, believe that performance appraisals are unnecessary and, in fact, may destroy initiative and encourage competitiveness rather than teamwork, process performance, and a concern for organizational success (2). Others contend that formal performance appraisal programs cost billions of dollars annually (1) for questionable benefits (1, 7, 8). Stress associated with the appraisal process is another reason cited for not conducting performance appraisals (1). In contrast, many human resource experts believe that by implementing a well-designed performance appraisal program, the competitive aspect can be minimized and the motivational aspect can be emphasized (6).

Disadvantages of performance appraisals include the following.

- Destroying initiative
- Encouraging competitiveness
- Creating negative experiences and inducing stress
- Natural biases resulting in rater errors
- Inexperienced evaluators
- Lack of participation from employees
- Large financial investment
- Significant time for planning and implementation, particularly from managers with many employees

Some managers and employees dislike and even dread performance appraisals. They go through the motions, albeit halfheartedly, because senior management requires them to participate in a formal appraisal process. Unfortunately, they do not realize the potential benefits that can be derived from performance appraisals, nor have they developed the skills necessary to conduct or participate in a productive performance appraisal process. An objective of this chapter is to provide you with an appreciation for the performance appraisal as a powerful motivating tool.

Advantages of Performance Appraisals

Appraisals can be challenging as well as productive, rewarding, and energizing (9). Positive feedback provides employees with the opportunity to learn their strengths and weaknesses. Employees can be empowered to control their growth and development, as well as the outcomes of the performance appraisal (10). If carefully performed, the appraisal process can enhance relationships with employees and open doors to communication. Managers and their

本书版权归John Wiley & Sons Inc.所有

employees can set realistic goals that reflect and support the mission and goals of the organization as well as the employees. Finally, the performance appraisal system and specifically the performance standards are objective tools to use as a basis for merit pay increases, promotions, and termination.

A successful performance appraisal promotes good communication and constructive feedback between managers and employees. It provides an opportunity to review, clarify, and/or modify job requirements and performance expectations. When used as an evaluation tool, the appraisal becomes a critical component of reinforcing appropriate behaviors and providing a fair, legal, and consistent foundation for promotions, transfers, demotions, terminations, and salary adjustments. An effective appraisal process can be used as a recruitment tool to attract candidates for employment into a program that recognizes employee contributions and accomplishments. Employers may highlight how their organization provides opportunities for skill development and promotion. Retention in today's market is important, given the dwindling work force that the laboratory continues to face. When employees feel valued, they tend to remain on the job as loyal employees. In summary, performance appraisals can be used as a tool to recognize outstanding employee achievements and to provide desirable work-related experiences and career opportunities for advancement.

Advantages of performance appraisals include the following.

- Promoting good communication
- Providing real-time feedback from both management and employees
- Identifying short- and long-term goals
- Improving employee performance and productivity
- Clarifying job requirements in an environment of rapid change
- Providing an opportunity to refine and/or retrain for changing job requirement skills
- Defining performance expectations with employee input
- Promoting behavioral modification with specific recommendations
- Recognizing the ramifications of stress and focus on employee well-being
- Identifying educational and training needs
- Providing documentation for promotion, compensation, and termination decisions
- Promoting recruitment and retention
- Assisting in downsizing/layoff decisions
- Protecting the organization from discrimination lawsuits
- Providing an opportunity to share departmental and organizational visions
- Encouraging teams to recommend improvements per organizational operations

Trends Beyond the Traditional Performance Appraisal

Most organizations are transitioning from the more traditional performance appraisal process to different areas of emphasis. There is increased focus on improving employee experiences within the performance appraisal process (11). Organizations are also recognizing the costs of stress; employee well-being has become a part of performance reviews. Employee professional development and career opportunities have been recognized and treated as major issues to be included in the performance review process. Organizations have begun providing more feedback on a continuous basis; this helps in mentoring employees rather than just focusing on past performance. These trends are relevant to healthcare employees and are seen as being improvements to the process (12). During the coronavirus disease 2019 (COVID-19) pandemic, it became clear that healthcare workers may not seek traditional support such as psychotherapy. However, the ongoing support for mental health and support needs for employees became critical and took on added importance to ensure the well-being of all personnel (13). These newer considerations need to be included in any approach to performance evaluations.

Appraisal Types: Formal and Informal Appraisals

An effective appraisal system may include formal as well as informal ongoing performance feedback. A formal performance appraisal generally occurs annually on a specific date and time, such as the anniversary of the employee's hire date (2, 4). Performance appraisals can also be given at a set time of the year identified by the human resources department for larger groups of employees within an organization. Appraising everyone during the same time frame is generally viewed as most fair because the same guidelines can be applied to all employees evaluated (1, 2). A performance appraisal form is generally completed during the interview, and this written documentation is placed in the employee's file as part of the permanent record.

In contrast, informal performance feedback appraisals are useful for monitoring behavior modification, recognizing accomplishments, identifying stumbling blocks in achieving set goals, giving support where applicable, and fostering ongoing communication between formal appraisals. This more informal process provides input within a mentoring system; consequently, commentary at the formal appraisal does not contain issues that have not been addressed prior to the formal process. Frequent informal appraisals ensure that the formal appraisal does not come

本书版权归John Wiley & Sons Inc.所有

as a surprise to employees. They know what is expected and can work at fulfilling those expectations. In the past, most mentoring relationships consisted of senior staff guiding the personal and professional growth of younger employees. However, in our current multigenerational workforce, rather than focusing on senior versus junior personnel, it is more important that mentors have experience that can help others learn and adapt to change. Assumptions underlying performance appraisals are often complex and interrelated (Table 13.1).

Benefits of informal performance appraisals include the following.

- Providing an opportunity to monitor behavioral modifications
- Allowing timely recognition of accomplishments
- Providing more informal opportunities for discussion (coaching, mentoring)
- Identifying stumbling blocks to achieving goals
- Providing continuous support, rather than a once-a-year focus on past performance
- Fostering ongoing communication
- Encouraging and supporting mentoring relationships rather than a single yearly review

Table 13.1 Performance appraisal assumptions[a]

Assumption	Reality	Alternate approach
A single appraisal process can serve several purposes at the same time.	A single appraisal contains numerous evaluation criteria that may conflict with one another (e.g., compensation vs negative comments).	The multiple purposes of the performance appraisal can be achieved through separate processes; one size does not fit all.
A single coaching, feedback, and development instrument works well for supervisors and employees in all situations.	Not all supervisors and/or employees respond the same way to the evaluation process.	Preferences regarding coaching, feedback, and career development vary among individuals; overall situations change over time.
The organization and supervisors are responsible for employees' feedback, performance, and career development.	Although empowerment is promoted by organizations, often the performance appraisal makes the supervisor rather than the employee responsible for the outcome.	People need to be responsible for their performance and development, with or without organizational support.
Appraisals can objectively and consistently assess individual performance.	The appraisal process is influenced by bias and rater errors; often information obtained is incomplete and/or unreliable.	Appraisals are highly subjective; multiple, more timely ratings associated with a single defined situation will be more valid and reliable than multiuse rating approaches.
Ratings provide motivation and let people know where they stand among the group.	Often rating information is neither helpful nor representative of the employee's true status; ratings also may undermine commitment and demoralize; everyone expects to be rated highly and their efforts appreciated.	In a supportive and mentoring work environment, employees will use more timely information to improve their performance, particularly if training and advancement opportunities are available; employees should have ready access to all information that impacts decisions related to pay, promotion, status, and future options.
Giving feedback related to employee development and performance is an annual (or quarterly) event.	Relevant feedback should be available all the time, not as a specific date-driven event. Improvement opportunities do not occur once a year, and employee development needs vary from one individual to another.	It is the employee's responsibility to solicit feedback at the most appropriate time; these discussions are variable and depend on the situation, individual needs, personal choices, and timing.
Employees limit or reduce efforts if they feel they are not being extrinsically rewarded.	People are intrinsically motivated to do a good job, although inadequate pay and recognition may be demotivating factors; rather than providing rewards, organizations need strategies that encourage intrinsic motivation that already resides in each employee.	For the most part, employees are intrinsically motivated to perform well when the work is meaningful; intrinsic motivation can be reduced by placing the focus on extrinsic motivators.
Evaluating individuals results in improvement; improving individual performance results in organizational performance.	Improving employees is often important but may not result in organizational improvements; improvement within the overall organization usually results from reviewing opportunities to understand the entire system that drives outcomes.	Organizational improvements result from problem resolution; identify the problem, study the cause, and determine specific opportunities for improvement, development of a plan, review of implementation, learning, and acting on information gained.

[a] Adapted from references 1 and 6–8.

本书版权归John Wiley & Sons Inc.所有

Responsibility for Developing a Performance Appraisal Program

The organizational philosophy and purpose of having performance appraisals should be clear to those who are designing a performance appraisal system. The performance appraisal program is frequently developed by one or more members of upper management and supervisory-level employees, including the chief executive officer, managers, human resource professionals, and staff employees, particularly those who are strong performers or who welcome new opportunities. There are several reasons for including staff employees in the planning process. First, they are intimately acquainted with the tasks that make up their jobs and with the factors that impact their ability to get the job done. If they know their input is valued, they will feel that their opinions matter and that they are an important part of the decision-making body of the organization. In turn, their involvement is likely to engender support for the program and loyalty to the organization. Finally, they will feel that they are being given a new opportunity to learn and advance in their careers (2).

Who is responsible for developing a performance appraisal program?

- Upper management
- Supervisors/managers
- Human resources staff
- Staff employees
- Human resources/management consultants (may or may not be a consideration)

Legal Aspects of a Performance Appraisal Program

The form that is used to document the performance appraisal may be a standardized form, or it may be created by human resources and/or organizational managers and staff (1, 7). Performance appraisals are discoverable in a court of law. In other words, the information may be considered evidence in a legal case, so it is important to always apply the performance appraisal process fairly and equitably (14). Discriminatory policies can and will get you in trouble (45); state and federal laws prohibiting discrimination can be found in appendix A of reference 15. Clearly defined standards, feedback, and documentation are key factors in defending your program and appraisals (4, 14, 15).

If you need to fire an employee, remember that the performance appraisal must support, document, and not contradict your justification for the termination. Although this may not be a consideration at the time of the appraisal, you cannot try to justify termination actions after the fact. In general, all employee evaluations, including the formal evaluation and other "check-in" performance assessments, must be documented (both good and bad) and discussed with the employee at the time.

Evaluating employees and awarding pay increases based on the evaluation scores are paramount to keeping your program defensible. Performance appraisals are confidential and should be shared with individuals other than the employee only on an as-needed basis, except by subpoena (2). The following factors help to ensure that you are using a legally defensible performance appraisal system.

With regard to appraisal documentation and actions, consider the following.

- Appraisers should receive written instructions and specific training on how to utilize the appraisals correctly.
- Job descriptions should be used to determine what is evaluated.
- Performance expectations should be reviewed in advance with the employee.
- Appraisals should be designed to evaluate behavioral criteria that can be measured, not personality traits.
- The content of a completed appraisal form should be discussed with the employee, and the employee in turn should have a chance to add his or her own comments.
- Everyone should be evaluated fairly and consistently.
- There should be no surprises at the performance review; any past issues should be documented and should have been discussed with the employee prior to the formal evaluation.
- The appraiser should tell the truth, be thorough, and document all assessments if the situation suggests the possibility of future termination.

The following steps are important with regard to legal considerations.

- Train appraisers.
- Review job descriptions and performance expectations prior to the interview.
- Evaluate behavior, not personality.
- Provide employees with an opportunity to respond to the appraisal.
- Make sure any performance problems and/or feedback have been previously discussed/documented with the employee.
- Evaluate fairly and consistently.
- Document appraisal in detail, particularly if you anticipate potential future termination.

本书版权归John Wiley & Sons Inc.所有

Elements of a Meaningful Formal Performance Appraisal

An effective appraisal program is based on an honest and sincere discussion of expectations, job performance, and plans for improvement and follow-up between appraisers and their employees. Performance appraisals must be clearly developed to meet the requirements of specific positions. It takes a concerted effort and up-front expense to develop and maintain an effective performance appraisal system. Time must be devoted to analyzing and preparing job descriptions for each job title within an organization; designing performance appraisal forms; executing a successful performance interview, including preinterview planning, follow-up (16, 17), ongoing monitoring, documenting, training, and compensation. An effective program requires total management commitment of time and money (1). Remember that the COVID-19 pandemic not only changed the way we work but also changed the ways in which we are recognized for our work. Also, we are working in an era in which the annual performance appraisal is being or has been phased out and is being replaced by a system comprising continuous learning, monthly check-ins, mentoring, continuous feedback, building trust, and establishing connection to the work community.

Elements of a formal appraisal (none of which is limited to an annual evaluation) include the following.

- Clear expectations: mission statement, job description, performance standards
- Valid and fair performance assessment
- Plan for improvement
- Follow-up

Mission statement. A meaningful performance appraisal should begin with a current organizational mission statement. The organizational philosophy should be incorporated into the mission statement of each performance appraisal. Understanding organizational goals and values is paramount to setting goals for the employees and ultimately to ensuring organizational productivity and success. As a manager, it is important that you convey the goals and values of the organization and department to your employees.

Job description. A job description is a written document that generally includes the title of the position; department; job code or number, if applicable; Federal Labor Standards Act status as to whether the position is exempt (salaried) or nonexempt (hourly), full-time, part-time, or temporary; job summary; four to six essential functions or tasks; level of authority; reporting relationship; essential skills or traits required to perform the tasks; qualifications; physical requirements; and effective date of the job description (2). All employees in an organization should have an up-to-date job description so they know what is expected of them (1).

A job description is a valuable tool when terminating an employee for failing to do the job. It provides documentation that the employee knew what was expected of him or her. "Essential functions" are those duties and responsibilities that are an inherent part of a particular job. The term is included to protect the rights of disabled workers under the 1990 Americans with Disabilities Act (ADA) and is applicable to organizations with at least 15 employees. The ADA is enforced by the Equal Employment Opportunity Commission (2). To meet legal requirements, a skill must be shown to be a job. The two controlling principles in developing written job descriptions and standards are job-relatedness and fairness (2).

Performance standards. Performance standards should be specific, measurable, and realistic.

Evaluations based on performance standards were introduced in the 1990s and are commonly used in the laboratory setting. Standards are formal requirements that outline expectations of job performance, i.e., how well a job should be performed. Performance appraisals must contain specific, measurable, and realistic standards of performance (4, 18). In other words, the job description defines the job responsibilities, and the standards quantify your expectations, e.g., how many cultures are read per day and percent errors tolerated. Standards can be used to compare the quality of work among staff members. Different types of jobs may call for demonstrable skills or behaviors rather than numerically quantifiable units of production. For example, a standard of performance in the laboratory may be to demonstrate familiarity with safety regulations to provide a safe work environment. Another method of measure is to include percent timeliness; e.g., technologists will finalize 75% of the 48-hour cultures on time. Established and specific performance standards allow employees to know how they are doing compared to expectations (10, 19). It makes them accountable (1).

Criteria. A criterion is a standard for judging task performance. Three or four specific, detailed, and realistic written criteria should be developed, understood, and agreed upon by employee and supervisor for each key task (4, 10). These need to be objective, observable, and measurable (18).

Norms. Norms (9) are informal behaviors that are generally accepted in the workplace. For example, treating coworkers with respect is an organizational norm. Norms are more difficult to identify and more subjective than standards. The problem with using norms to measure

本书版权归John Wiley & Sons Inc.所有

employee performance is that they are subjective. A behavior may be considered acceptable to one manager and unacceptable to another. Alternatively, a manager may consider a behavior to be acceptable when exhibited by one individual and unacceptable when exhibited by another individual. Norms are not less important than standards, because violations of an organization's norms can have as much impact as violations of its standards. For example, one of your employees may exceed all standards but frequently offend or insult other coworkers. As a manager, you may find yourself repeatedly calming the other coworkers as a result of the ongoing violation of the laboratory's norms. In this case, when the violation of a norm interferes with the performance of other employees, the individual violating the norm needs to be counseled.

Competency-Based Appraisals

Appraisals are often position specific and competency based using observable and measurable standards. The Joint Commission (TJC) initially required employers to use criterion-based performance appraisals and later replaced the requirements with competency-based appraisals. In other words, performance appraisals must ensure that all healthcare workers are competent in all areas necessary to perform their jobs. Competency is the state of having the correct or needed skills for the position. In a competency-based performance appraisal, each required competency should be evaluated in some quantitative format. Appraisal forms that use a rating system with a structured scale generally are easy to complete. The disadvantage of a rating system is that it tends to set up a competitive feeling among employees. The most recognizable company to have used a rating system is General Electric. Managers would evaluate employees by dividing talent into three groups—a top 20%, a middle 70%, and a bottom 10%. The bottom 10% were considered low achievers and were usually the ones let go. This created an environment of competition rather than one of collaboration. It is important that the appraiser qualify a rating with behavioral examples. For example, if you score an employee above or below what is considered the minimally acceptable score, you should provide written details.

Rating Methods

The validity of a rating system depends on such things as rater training and observable and quantifiable behaviors. Employees should have a current, detailed job description and know performance standards and criteria used for assessing performance. Appraising an employee's performance means that you are rating actual performance, not ability. A person may have the ability but may not be performing up to the standards set for that job. Characteristics commonly assessed are competency, accuracy, communication, creativity, productivity, problem solving, decision making, delegating, and administrative effectiveness. You must be able to consistently observe the employee performing the assigned tasks, and your rating criteria must be the same for all employees doing the same job. Performance must be described accurately and must be based on documentation. Be careful when rating subjective qualities such as attitude, cooperation, enthusiasm, and initiative. A qualitative characteristic such as interpersonal skills may be appraised as, e.g., unsatisfactory (fails to meet acceptable standards in relationships with others), average (gets along well with others), or outstanding (excels in developing relationships of trust and respect with supervisors and peers) (1). Quantifiable performance measures, such as the number of times STAT turnaround times were within acceptable limits, specimens were processed, critical values were called, and errors were made and percent of time within budget, are productive measurements that are easier to defend.

Results-based evaluations (RBEs) are performed by managers who focus on attainment of specific measurable results. RBEs may be used in intangible areas such as attaining specific goals in management development, reaching personal goals, and collaborative efforts. Key results areas and expectations are agreed upon at the beginning of a period and measured regularly by staff submittal of monthly progress reports. This type of evaluation allows a manager and employee to set and prioritize reasonable goals.

A rating system may be used to compare the performance of employees through a set of criteria that produces a numerical value (4, 20). There are four factors to consider when designing a written performance appraisal and selecting a rating system: the purpose of the appraisal, your work environment (e.g., self-directed teams), verbal and analytical skills of the employees being evaluated, and the manager's management style (4). Rating requires clear definitions of the terms "exceeds standards," "meets standards," and "does not meet standards." Absolute methods include a graphic rating scale, critical incident evaluation, a behaviorally anchored rating scale, and use of a checklist.

A graphic rating scale provides a ranking scale (usually 1 to 5) for unsatisfactory to outstanding performance (4). An overall rating can be calculated by averaging the individual rankings. This is one of the most popular methods, as it is easy to use and understand, the forms are easy to revise, and the method is not usually time-consuming.

Free-form or narrative rating (4) is generally an adjunct to other methods (1, 2, 21). A variation of this rating is the critical incident evaluation—documenting written notations of exceptional performance, good or bad, that are then summarized in the written performance evaluation (21). A disadvantage is the lack of reference to the day-to-day, noncritical performance that makes up the greatest portion of an employee's on-the-job behavior (Table 13.2).

本书版权归John Wiley & Sons Inc.所有

Table 13.2 Rating system pros and cons

Appraisal method	Pros	Cons
Rating scale	Many managers and employees are familiar with them Simple way to communicate areas of strengths and weaknesses Ease of use and understanding	The assumption that they are directly tied to an employee's raise or bonus Managers can also have negative bias toward employees
Narrative technique	Can focus on praising positive behavior and addressing areas for correction Thoroughness of detail in analyzing employee behaviors	Employee might interpret the evaluation too positively or too negatively relative to a scoring system
Comparison method	Can motivate performance in competitive workplaces and among competitive employees Allows you to communicate to an employee about areas in which he or she over- or underperforms relative to others in similar positions	The potential for infighting and the lack of harmony in the employee ranks
360° feedback	Allows a better chance to compare different perspectives in the evaluation process Offers the employee a glimpse of how others view his or her performance in various relationships critical to the job	Biased evaluators Negative employee feelings Poor alignment with goals

A behaviorally anchored rating scale (BARS) entails writing a competency statement for each aspect of the job. The BARS (20) focuses on employee behaviors and avoids any evaluation of attitudes. A numerical rating scale is used with a description of behaviors that correspond to each of the ratings (21). It is based on critical incidents or actual examples of how employees behaved in a particular situation. This type of rating is generally more expensive and time-consuming to implement. It is also more difficult to develop, because it must identify all work behaviors of a job with a specific description of each behavior, ranging from unsatisfactory to outstanding.

Checklist adjective evaluation is based on the use of descriptive phrases to describe a laboratory worker's most outstanding personal characteristics (4). Checklists include statements describing positive and negative behaviors that may be exhibited on the job. If the employee exhibits one of the described behaviors, the item is checked off; if not, the item is left blank. With a weighted checklist, behaviors are weighted differently instead of being considered of equal importance. Points are assigned based on the organizational value placed on that behavior.

Forced-choice rating is not commonly used. A rater chooses the most applicable of several unrelated descriptions of performance. The choices are purposefully difficult, with the intent of improving the reliability of the rating (9).

Comparative methods used in the 1980s included forced distribution, ranking employees, and paired comparison. Forced distribution (4, 9, 10) requires the rater to distribute a certain percentage of employees in each ranking category, e.g., 5% outstanding, 10% above average, etc. (10). This helps an organization control and forecast salary budgets.

In a ranking, employees are compared and ranked numerically from best to worst among their peers. Because it is not possible for all employees to be ranked as excellent even if they are, a ranking system (4, 9) does not provide feedback about the employees' performance and generally is neither reliable nor valid.

In paired comparison, employees are compared two at a time (4). Ranking occurs on the number of times a given employee is deemed to be the better performer of a pair.

Person-to-person comparison is comparable to paired comparison. Employees are ranked below average, average, above average, or outstanding on the basis of comparison of their performance with that of peers who are currently performing similar tasks (4).

In summary, absolute methods of ratings and ranking include the following.

- Graphic rating scale
- Free-form evaluation
- Critical incident evaluation
- Behaviorally anchored rating scale
- Forced choice
- Forced distribution
- Paired comparison
- Person-to-person comparison

Other Types of Performance Appraisals

Self-appraisal. Self-appraisal forms are generally distributed approximately 2 weeks prior to a formal appraisal and are not meant to take the place of a manager's appraisal. They give a different perspective of an employee's performance and possibly a better understanding of the potential obstacles that may impede performance. Employees may be provided with a copy of the form used by the manager so that they can use the same criteria for evaluation of their performance. Ratings and scores can then be easily compared. Interestingly, most employees tend to appraise themselves at the same level as or lower than their manager

本书版权归John Wiley & Sons Inc.所有

does (2). As an alternative, some laboratories design a form with a different format that elicits additional information by asking open-ended questions (2). The self-appraisal generates active participation by employees. It provides an opportunity for employees to reflect on their own performance and achievements (10). They may identify additional accomplishments that the manager may not have identified or may have forgotten. The self-appraisal also promotes a two-way conversation regarding the need for additional training and development (1, 21).

Peer-to-peer appraisal. Peer-to-peer appraisals require trust among employees working together. Coworkers are asked to evaluate each other. There are obvious pros and cons for this approach, and many organizations do not use this type of appraisal. This approach may engender fears among staff members, some without foundation, which need to be addressed. A comprehensive training program on how to give feedback is required to successfully implement this type of appraisal (2). The technique may be risky when conflict exists among employees, thus preventing an objective evaluation. Conversely, if you are working with an experienced and mature group of employees, the process may be very educational. If the appraisals are performed honestly and sincerely, employees may gain great insight into their work relationships and performance. If you are using a team approach to accomplish institutional goals, you may want to consider a variation of this concept. One team of employees may be asked to evaluate another team, rather than appraising individual coworkers.

360-degree evaluation. 360-degree evaluations are designed to obtain well-rounded appraisals that tend to be reserved for individuals in management-level positions (9). As with peer-to-peer evaluations, both trust and a comprehensive training program are required to successfully implement this technique (2). The evaluation is often performed anonymously and invites open, constructive in-depth feedback from all levels, i.e., peers, subordinates, supervisors, customers, and self (1, 18). Raters are frequently asked to complete a series of open-ended questions. Solicited evaluations with rater identity removed may be given to the employee being appraised, or they may be summarized to obtain an overall feedback appraisal. This type of evaluation is used for developmental purposes, not for salary adjustments (Table 13.2).

Who Should Perform the Appraisal?

The appraiser should be a direct observer of work performance in order to give a credible appraisal (2). He or she should have a firm foundation in what needs to be accomplished to get the job done successfully. Some managers will ask for input from other individuals who interact with the employee being evaluated to ensure an unbiased appraisal. Just remember that sincerity and honesty are the keys to a successful performance appraisal.

Preappraisal Preparation

Appraiser. Approximately 2 weeks before the performance appraisal, appraisers should schedule the appraisal in a comfortable, nonthreatening, neutral location where there will be no interruptions (16). Prepare for the meeting by reviewing your documentation and the employee's self-appraisal and/or list of accomplishments (1, 4, 16, 21–23). Make the appraisal a priority and start on time. It is advisable to sit next to the employee, rather than across a desk, to encourage open conversation. Refrain from taking phone calls during the interview. Allow enough time (at least 1 hour) to complete a formal appraisal (2, 9).

Preparation steps the appraiser should take are as follows.

- Schedule meeting
- Select neutral location
- Prepare/review documentation
- Start on time
- Hold phone calls
- Allow enough time

Employees. Employees should be on time for the meeting. Self-appraisals should be submitted to the manager well in advance so that the manager has a chance to review the information before the formal appraisal meeting. Employees should review their job description, the standards for the position, the organizational mission statement, and their goals and accomplishments (18, 23). They should connect their goals with the organizational goals (2). Employees should prepare a list of goals for the coming year and should discuss any obstacles that might impede the accomplishment of those goals. They should be prepared to suggest a solution to a problem. Goals should be established that stretch the employees' capabilities. Employees should be forthright, positive, and honest and provide feedback to their managers. Employees should listen and be open to suggestions. They should ask for specifics and clarification if they believe the appraisal is not reflective of their performance. When given the opportunity to provide written comments, they should document any specific disagreements on their performance appraisal form (1, 23).

Preparation steps the employee should take are as follows.

- Complete self-appraisal
- Review job description, performance standards, mission statement, goals, and accomplishments

本书版权归John Wiley & Sons Inc.所有

- Relate personal goals with organizational goals
- Prepare list of future goals
- Identify obstacles
- Provide feedback
- Listen and be open to suggestions
- Ask for specifics and clarification

Steps to a Successful Performance Appraisal Interview

Preliminary meeting with employee. The purpose of the meeting is to explore ways to achieve personal and organizational goals and make improvements. Begin the interview by initiating a friendly conversation to put the employee (and yourself) at ease. Explain the purpose of the performance appraisal and review the organizational and departmental mission statements, the job description, the performance standards, the goals of the organization and those previously set with the employee, and the self-appraisal before beginning the formal interview. Remember that performance appraisals should hold no surprises and should not be punitive. Reinforce that the overall intent is for feedback to be motivational (2). Instead of covering every point on the form, be more conversational, because the employee will receive a copy of the form to read later.

Formal meeting. Approach the performance appraisal in a positive and respectful manner. The performance appraisal process should motivate employees and should encourage their feedback, so don't do all of the talking and don't answer your own questions. Ask open-ended questions to stimulate discussion and obtain employee responses (2). For example, you may ask questions (48) such as, "What is your understanding of the performance expectations?" "Do you need more training?" "What kind of support can I provide for you to help you accomplish your goals?" Listen actively and intently, do not interrupt, and give feedback. Summarize comments made by the employee during the discussion to ensure that you understand what the employee is conveying to you. Be forthright and constructive in your evaluation, but not critical. Now is not the time to be timid. Most employees have some room for improvement. Using the halo effect (1, 2, 9, 16, 18), whereby you give positive performance appraisals even when undeserved, does nothing to stimulate behavioral modification (1). Likewise, avoid the pitchfork effect (9, 18), whereby a single instance of poor performance adversely affects your overall assessment.

If you point out deficiencies without a plan for improvement, the employee may leave the meeting not knowing how to change the situation (18). The result is that you will not see behavioral modification. Even if behavior modification is needed, focus on how you and your employee can work together to create a positive outcome. Set goals (generally at least four) for the coming year and help the employee specify the behaviors that must be changed to meet these goals. The goals should be realistic, but at least one of them should be a stretch (2, 16, 18, 24). It is important that you communicate with your staff daily and keep them informed. Listen to them, don't micromanage, and share your vision and the organization's vision. Celebrate small and large victories and be generous with your praise. Finally, treat others with respect.

At the beginning of the meeting, inform the employee that you may refer to your notes and that during the discussion you may take notes that will become part of the personnel file. Let the employee know that he or she will have an opportunity to review your written summary, add statements to the document, sign it, and receive a copy before you place it in the personnel file (2). If the employee refuses to sign the performance appraisal, document this and sign the form along with a witness. Also include the date of the meeting and a summary of the agreements you have made. Set follow-up dates and make sure you keep the appointments (21). Disciplinary sessions should be scheduled separately from the performance appraisal. The "do's" and "don'ts" of a performance appraisal (2) are summarized in Table 13.3.

Table 13.3 Do's and don'ts when conducting a performance appraisal[a]

Do's	Don'ts
Prepare ahead	Use the appraisal to discipline for past negative performance
Explain the purpose of the appraisal	Focus on personality issues
Review the mission statement, job description, standards, and goals	Make gender-based statements
Focus on performance	Generalize
Provide specific performance examples and offer actions	Use subjective language
State impact or consequences of behavior	
Communicate sincerely	
Ask open-ended questions	
Listen to the employee	
Summarize to ensure understanding	
Encourage feedback	
Be objective and use objective language	
Be as clear and concise as possible	
Use examples of behaviors you observed	
Set new goals and standards	
Develop an action plan	
Document the appraisal	
Follow up	

[a] From reference 8.

本书版权归John Wiley & Sons Inc.所有

Steps for the appraiser to take during a formal appraisal include the following.

- Observe directly
- Rate behavior
- Measure productivity
- Determine if specific goals have been accomplished
- Establish organizational initiatives
- Identify incidents
- State impact or consequences of behavior
- List additional training received
- Identify future goals

If managers lack the skills necessary to execute an appraisal, they should receive training in how to effectively give feedback to staff members (2). Training should include a review of the organizational philosophy and the purpose of the program and should cover how to complete the forms and score the evaluation (4), give feedback in a positive manner, focus on performance and not personality, coach for improvement (1, 3, 7, 8), make wage and promotion decisions using performance data, and discover weak spots and correct them. Establish a list of words or phrases to be used for coaching and appraisal discussions (9, 25). Some organizations provide this training at orientation for new managers and annually thereafter.

Appraiser training should include the following.

- Review organizational philosophy
- Understand purpose of performance appraisals
- Know how to complete the form and score the evaluation
- Provide feedback in a positive manner
- Focus on performance, not personality
- Coach for improvement
- Understand how to make wage and promotional decisions based on performance appraisals

Benefits of Becoming a Mentor

The appraisal process can be a forum for career development by focusing on employee development, coaching, and training needs. You may, in fact, take on the role of a mentor or trusted advisor to your employees. A mentor typically shares information, experiences, and lessons in leadership. You must believe in your employees and encourage, support, and coach them to aspire to higher goals. Proudly represent your employees to others, lead by example, and exhibit a positive attitude. Mentors tend to take a big-picture approach, getting involved only when help is requested. Mentors thus become a positive force in employee career development (2). This approach is becoming more widely used as the formal annual performance review is being modified or phased out (5, 6, 11).

Mentor responsibilities include the following.

- Sharing information and experiences
- Believing in your employees
- Encouraging, supporting, and coaching your employees
- Proudly representing your employees to others
- Leading by example
- Exhibiting a positive attitude

Salary Adjustments

Merit increases usually are the result of formal performance appraisals that connect levels of performance with varying levels of salary increase or performance incentive. It is better to have separate meetings for the performance appraisal and salary increase so that you do not run the risk of feeling pressured to start the conversation by announcing a salary adjustment and then justifying your decision (9, 16).

Strategies To Reinforce Appropriate Behaviors

According to the law of effect, behaviors that are followed by positive consequences are more likely to be repeated. Providing positive consequences or rewards increases the probability that an appropriate behavior will be repeated (1). To be effective, however, positive reinforcement should be applied as soon as possible following the behavior and must be contingent on the desired behavior. This is one reason why informal appraisals are crucial to the success of the appraisal process; the employee does not have to wait a year to learn which behaviors are appropriate and which are inappropriate.

Guidelines for Appraising Poor Performers

Don't wait until appraisal time to address poor performance. You should have documentation of coaching to address problems throughout the year. Ensure that the employee has a current copy of his or her job description and performance standards. During the interview, give examples of poor performance to support your assessment and the consequences of the behavior (2). This can best be done by providing documentation of how the employee's work does not meet standards and by reviewing previous discussions you may have had with the employee regarding the problem. Prepare a list of specific changes you would like him or her to make and the time frame in which to correct the behavior. Present the information in a manner that shows confidence in the employee's ability to improve. Set measurable standards for improvement and plan together how this can be accomplished. It is important that you plan on meeting in the interim to review the improvement and assess and encourage the employee. Remember, frequent check-ins and a more mentoring approach are more likely

本书版权归John Wiley & Sons Inc.所有

to place the focus on future improvements rather than past performance problems (5, 6, 11). According to the Growth Divide study conducted by Wakefield Research, almost 94% of the employees prefer performance feedback and improvement opportunities in real time. It is important to remember that there is a positive impact on performance if the appraisals are frequent, informal, and integrated with work (26).

Dealing with Emotional Outbursts during Performance Appraisals

If the employee engages in an emotional outburst or demonstrates signs of aggression, the manager should deal cautiously with the individual and should have another manager come to the room. You may want to encourage the employee to seek assistance, and you may need to reschedule the meeting. If you anticipate an interview with a negative employee, spend extra time preparing for the meeting. This may require consultation with human resources on how to deal with out-of-control employees. It is important that you do not respond emotionally to an employee who is out of control (21). Results of performance appraisals can incite emotions that sometimes are difficult to deal with. For example, crying or shouting may call for a postponement so that the employee can regain his or her composure and the appraisal can be productive. Employees can disengage either due to the appraisal or for personal reasons. You will need to conduct an intervention as soon as possible, particularly if you are interested in retaining the employee. Performance appraisals can be a positive experience only if the relationship between the employee and their supervisor/manager is intact. If there is a history of inappropriate behavior (i.e., harassment, abuse, or violence in the workplace) with an employee's immediate supervisory group, then the option should be available to the employee of bringing a supportive person (i.e., peer, colleague, etc.) with them to the interview, and a Human Resources representative should also be present in these cases. Toxic workplaces are created when an employee is repeatedly harassed but management does nothing or, even worse, the behavior is being perpetrated by management. One needs to therefore understand the basis of an employee's emotional reaction—crying, shouting, etc.—rather than merely calling the employee "out of control."

Completed Performance Appraisal Documents

A fully executed written appraisal is a complete and confidential original document, with any changes, added comments, and signatures in place (2). The feedback documentation format should be flexible enough to record information discussed during the appraisal; you may need to improvise and expand the template. The original document should be placed in the employee's personnel file and kept in a secure place for the number of years that is specified by organizational policy. Employees should be given a completed copy for their records. Finally, the manager should keep a copy in his or her files.

Requirements for performance appraisal documents include the following.

- Maintain confidentiality
- Emphasize specific employee achievements
- Provide fair, objective, and detailed feedback as part of written documentation
- Add a concise summary, including performance rating, key findings, future goals, training/retraining recommendation, and future expectations
- Include supporting documents (ongoing feedback during the year)
- Complete original, sign, and date
- Place original with human resources; this may/may not be relevant for your organization
- Keep documents according to policy
- Provide a copy to the employee during your comprehensive discussion/review of the appraisal content
- Place a copy in the manager's file for internal use and for accrediting agency review

Improvement Plan

One of the most important points of the appraisal form is to document feedback and improvements (1, 21). An improvement plan may be added to the performance appraisal form to identify ways to help an employee improve or attain a higher level of performance. Courts tend to rule more favorably when an organization assists poor performers in improving their performance. Examples of ways to improve performance may include working side by side with a more experienced technologist, attending continuing education programs, and working in another section of the laboratory to understand how each section is related to other sections.

Web-Based Software Products and Websites

Software can be purchased to automate the performance appraisal process (Appendix 13.1). A software program may provide action plans for an employee who is rated below average for a task. Although software programs may make it easier to execute appraisals, the downside is that they tend to decrease interpersonal communication, one of the key factors in a successful appraisal program. Available software may include one or more of the following sections: 360-degree feedback, compensation management, individual development plans, self-assessment, and/or skills assessment. Techniques such as coaching; personal development options; performance appraisals; specific, measurable, achievable, relevant,

本书版权归John Wiley & Sons Inc.所有

timely (SMART) objectives; objective management; rewards; and incentives represent some of the effective performance techniques available. Overall, these programs are designed to track employee performance in a way that can be quantified. Tips when considering such options should include the following.

- The software should have a modern, user-friendly interface.
- Reporting formats should be visually organized, robust, flexible, and able to provide employees and management with relevant performance metrics.
- Reports must contain relevant data that help identify top performers and required areas for improvement/development.
- The program should support integration with other appraisal tools and third-party applications.
- The cost should be appropriate for the included features; pricing plans must be clear and flexible (pay per user, pay per employee, or pay per plan).
- If program training is required, consider the following: training time/requirements, on-site or not, responsibility for any personnel training costs, and system complexity and/or simplicity.

Competency Assessment

Even though laboratories regularly evaluate the performance of their employees for the purposes of determining salary increases and job promotions, a regulatory requirement to have an objective system to document employee competency did not exist prior to 1988. Although external proficiency testing is a measurement of the ability to achieve a desired outcome for a particular analyte, it is not synonymous with competency. What is competency? TJC defines competency as a determination of an individual's capability to perform up to defined expectations (27). Another helpful definition of competency is the ability to do a job correctly and safely and to recognize and solve minor problems without needing assistance.

Regulatory Foundation for Competency Assessment

Assessment of personnel competency is mandated by federal statute and is a component of the accreditation programs of the College of American Pathologists (CAP), The Joint Commission (TJC), and the Commission on Office Laboratory Accreditation (COLA). This section reviews the specific regulations.

A federal statute resulted from passage by Congress of the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and subsequent signature by the president of Public Law 100-578 (28). CLIA '88 (29) classifies commercially marketed *in vitro* diagnostic tests into three levels of complexity (waived, moderate, and high) and defines qualifications for personnel performing testing across the spectrum of sites in which testing is performed (i.e., qualifications are site neutral). The CLIA '88 personnel standards provide a number of routes for individuals with diverse educational and training backgrounds to meet the federal regulations. To provide quality assurance for personnel within this framework, the laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for ensuring employee competence (42 CFR Sec. 493.1713).

CLIA '88 charges both the laboratory director and the technical consultant or technical supervisor with specific responsibilities for the competency assessment program of the laboratory. Policies and procedures should address the entire testing process, including preanalytical, analytical, and postanalytical phases.

Through the Laboratory Accreditation Program (LAP), CAP provides inspection checklist guidelines (17) that address employee training and experience, performance reviews, and competency assessment (Table 13.4). In 1996, TJC initiated a standard to be used by hospitals to assess, document, and improve the competency of all employees. The standards focus on job-specific, measurable, demonstrated, age-specific competency statements (30). In addition, TJC standards specify the responsibilities of laboratory management pertaining to the assessment and maintenance of employee competency and ongoing learning and development (27). For office-based laboratories, COLA requires that the laboratory director or technical consultant periodically evaluate personnel performance (31).

Timing of Competency Assessment

CLIA '88 mandates that the technical consultant of a laboratory performing moderate-complexity testing (42 CFR Sec. 493.1413) or the technical supervisor of a laboratory performing high-complexity testing (42 CFR Sec. 493.1451) be responsible for evaluating and documenting employee performance at least semiannually during the first year of employment. Subsequent evaluations are to be performed annually unless test methodology or instrumentation changes have occurred, in which case, prior to reporting patient test results, the individual's performance using the new test methodology or instrumentation must be evaluated.

Upon employment, all new hires should participate in a laboratory orientation program to ensure that patient test results will not be reported until the desired skill level has been demonstrated. An orientation checklist may facilitate this process and may help to ensure standardization when multiple trainers are involved. Orientation may encompass a variety of activities such as reviewing laboratory procedure and policy manuals, observing the procedure being performed, performing the procedure under

本书版权归John Wiley & Sons Inc.所有

Table 13.4 CAP checklist items pertaining to competency[a]

CAP item	Requirement
GEN.54400 Personnel Records (phase II)	Personnel files are maintained on all current technical personnel and personnel records include all of the following items. 1. Summary of training and experience 2. Copy of academic degree or transcript 3. License if required by state 4. Certification, if required by state or employer 5. Description of current duties and responsibilities as specified by the laboratory director a. What procedures the individual is authorized to perform b. Whether supervision is required for specimen processing, test performance or result reporting c. Whether supervisory or director review is required to report patient test results 6. Records of continuing education 7. Records of radiation exposure where applicable (such as with *in vivo* radiation testing), but not required for low exposure levels such as certain *in vitro* testing 8. Work-related incident and/or accident records 9. Dates of employment
GEN.54750 Testing Personnel Qualifications (phase II)	For laboratories subject to U.S. federal regulations, all testing personnel meet CLIA requirements.
GEN.55400 Visual Color Discrimination (phase I)	Technical personnel are tested for visual color discrimination.
GEN.55450 Initial Training (phase I)	There is documentation that all staff have satisfactorily completed initial training on all instrument/methods applicable to their designated job.
GEN.55500 Competency Assessment (phase II)	The competency of each person to perform his/her assigned duties is assessed. Elements of competency assessment include but are not limited to: 1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing, and testing 2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records 4. Direct observation of performance of instrument maintenance and function checks 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples 6. Evaluation of problem-solving skills
GEN.57000 Competency Corrective Action (phase I)	If an employee fails to demonstrate satisfactory performance on the competency assessment, the laboratory has a plan of corrective action to retrain and reassess the employee's competency.

[a]From reference 17.

supervision, and completing a posttest examination. A guideline from the Clinical and Laboratory Standards Institute (CLSI) provides a framework on the basis of which the laboratory may develop a program for training verification (32). The length of time required for orientation will vary depending upon the employee's formal training and work experience and the number of test procedures to be mastered. CLIA '88 (42 CFR Sec. 493.1425 and 42 CFR Sec. 493.1489) specifies that training of testing personnel must ensure (i) the skills required for proper specimen collection, including patient preparation (if applicable) and labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens; (ii) the skills required for implementing all standard laboratory procedures; (iii) the skills required for performing each test method and for proper instrument use; (iv) the skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (v) a working knowledge of reagent stability and storage; (vi) the skills required to implement the quality control policies and procedures of the laboratory; (vii) an awareness of the factors that influence test results; and (viii) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

Both the employee and the trainer must sign the documentation showing the specific training performed and the skill level attained. This documentation is maintained in the employee's file.

Accrediting agencies such as CAP and TJC require that competency of testing personnel be maintained on an ongoing basis. In addition to changes brought about by technological advances that may affect specific laboratory procedures or instrumentation, changes may also occur in the mission of an organization as delivery of healthcare evolves. To meet these challenges, ongoing education may be offered through a variety of formats, such as in-service

本书版权归John Wiley & Sons Inc.所有

educational programs, on-the-job training, audioconferences or teleconferences, self-instructional materials, local or national workshops, and local or national professional meetings. Documentation of the educational event, including the topic, date of presentation or participation, name of the presenter or trainer, and the individual participating, should be maintained in the employee's file as supporting evidence of ongoing competency.

Timing of competency assessments is as follows.

- Semiannually during first year for new employees
- Annually for all employees
- Preceding implementation of new methods or instrumentation

Methods for Assessment of Competency

CLIA '88 standards for assessment of personnel competency are the same for laboratories performing moderate- or high-complexity testing (42 CFR Sec. 493.1413 and 42 CFR Sec. 493.1451). The procedures for evaluation of competency must include, but are not limited to, (i) direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing; (ii) monitoring the recording and reporting of test results; (iii) review of intermediate test results or worksheets, quality control records, proficiency test results, and preventive maintenance records; (iv) direct observation of performance of instrument maintenance and function checks; (vi) assessment of test performance through testing of previously analyzed specimens, internal blind testing samples, or external proficiency testing samples; and (vi) assessment of problem-solving skills.

Accrediting agencies such as CAP and TJC will verify that all six required elements were used for the competency assessment for each test system.

Other than this requirement, CLIA '88 does not specify in detail how competency assessment should be accomplished, in order to preserve flexibility for laboratory managers to design programs that will meet their own unique needs. Examining, documenting, and continually expanding the competency of staff are essential for maintaining test quality, particularly in an environment in which allied health training programs are closing and the workforce is downsizing. When designing a competency assessment program, laboratory managers must determine which assessment method(s) will best suit their needs (14). Assessment may target functions identified as problem-prone or critical functions in which errors are likely to go unnoticed (18). It is the intent of CLIA '88 and TJC that competency assessment programs be grounded in staff development (27) and efforts geared toward quality improvement (33). The assessment plan should be designed to give objective measurements (8). The assessment plan should also delineate who will conduct the assessments. Senior technologists proficient in a subspecialty area may be recruited to perform subspecialty evaluations (34), or experienced staff members may be trained in performing and documenting competency assessments (35).

Direct observation of technical skills is especially useful for procedures that are manually performed, such as primary plating of cultures and venipuncture procedures. A checklist of predetermined skills will enable systematic documentation of the critical procedural steps under review (36). Direct observation is also indicated for monitoring performance of instrument maintenance and function checks.

Preliminary and final result worksheets, reported patient results (in either online or hard-copy format), quality control records, proficiency test results, and instrument preventive maintenance records should be reviewed as part of the quality assurance program of the laboratory. Documentation of the review is the essential component that will satisfy the competency regulations.

Assessment of test performance may be accomplished using previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. An example is CAP's HistoQIP tool, in which histotechnologists submit slides for various tests, such as a hematoxylin-and-eosin (H&E) stain of a breast core biopsy sample. The slides are evaluated by an expert panel for histologic technique, and the participants receive constructive feedback, peer comparisons, and benchmarking data. Given the limited amount or number of samples provided in external proficiency testing programs, a laboratory with many employees may need to utilize a combination of several methods to assess test performance. In one hematology laboratory, an exam based on microscope slides proved to be better than one based on color transparencies for improving daily practice skills (37). In the microbiology laboratory, retention of challenging Gram-stained smears (e.g., unusual organisms, Gram-negative diplococci in blood cultures, cerebrospinal fluid, or other body fluid with occasional organisms present) can be used for a microscope slide-based competency evaluation.

Digital imaging is widely used by pathologists for creation of static images using microscope-dedicated optical cameras and, more recently, using smart phones (38). The introduction of whole-slide imaging in 1999 provided the opportunity of digitally converting the entire tissue on a glass slide to a high-resolution virtual slide. In the last 2 decades, we have witnessed an exponential growth in the technology for acquiring virtual slides as well as its applications in various subspecialties of pathology. An addition to proficiency testing in pathology has been the use of digitized slides (https://www.aab-pts.org/ [accessed 14 August 2022]). Various sections where digitized slide proficiency testing and competency assessments are in use include bacteriology,

本书版权归John Wiley & Sons Inc.所有

cytology, histology (anatomical pathology), flow cytometry, hematology, immunohistochemistry-tissue microarrays, parasitology, and reproductive medicine.

A TJC standard requires assessment of patient age-related competencies of staff providing direct patient care (27, 39). This standard is therefore applicable to laboratory phlebotomists, whose practices vary with the patient age group. A continuing education exercise pertaining to age-specific phlebotomy techniques has been published (40). Demonstration of problem-solving skills may be assessed through self-reports of problem resolutions submitted by the employee. For example, if the quality control of an assay is outside expected limits, an employee can report the corrective action taken to achieve quality control results within range. Documentation of the steps taken to resolve receipt of unlabeled or mislabeled specimens is another example of problem-solving skills. Alternatively, an employee may complete a written exercise indicating how he or she would resolve an issue (41). This documentation should be maintained in the employee's file to support ongoing competency.

The laboratory's competency assessment plan should include procedures to address an employee's failure of the assessment. These procedures should include the time frame for retraining and reassessment and the expected outcomes (27, 42).

Practices

Practices of employee competency assessment are reflected in data from an interlaboratory survey in 2000 (43). In this study, employee competency was evaluated through the use of test and quality control results (77.4%), direct observations (87.5%), instrument preventive maintenance (60.0%), and written testing (52.2%). In 77 to 95% of laboratories surveyed, the supervisors/managers performed the competency evaluation of employees, whereas in 19 to 31% of laboratories, the evaluations were performed by peers. Delegation of competency assessment may be necessary to execute the plan. If the employee failed the competency evaluation, in 52% of laboratories, the employee was retested within 4 weeks, while in 8.6% of laboratories, the policy was to disallow the employee from continuing usual work. Adherence to the plan was inversely related to the number of full-time equivalents, the total number of employees, and the number of supervisors in the laboratory. There was less compliance with the plan in teaching hospitals than in nonteaching hospitals. These data indicate that difficulties may occur in completing the assessment of each employee each year as the size and complexity of the laboratory increase.

TJC requires that hospitals provide annual competency evaluation of employees in fire safety, infection control, and blood-borne pathogens. Beyond traditional lectures or written self-study modules, computer-based programs can be a cost-effective and efficient method of providing and documenting this assessment. This approach offers uniform presentation and 24-hour availability, features that are particularly helpful in healthcare organizations that must assess staff on three different work shifts.

Personnel Excellence

In addition to specific competencies reflected in job skills and knowledge, managers and executives should encourage professionalism, accountability, and self-esteem as competencies required to ensure customer service (44). These three competencies form the foundation of a hierarchy of all other generic competencies. In the 21st century, the quality and success of a laboratory depend on selecting, developing, and retaining competent staff.

SUMMARY

In summary, always remember that a successful performance appraisal recognizes people as the most valuable resource of an organization. The most important reason for doing appraisals is to focus on the future and motivate your employees positively. Recognizing accomplishments is a powerful way to motivate. Providing performance appraisals will show employees that you and the organization are interested in their work and in their development. An integral part of assessing employee performance is a well-designed competency program. Documentation of each employee's job-related competency is one way that a laboratory can not only ensure quality results but also fulfill federal and accrediting agency requirements.

KEY POINTS

- Performance appraisals may be powerful motivating tools that are closely integrated with compensation, training, and career planning.
- An effective appraisal system includes formal and informal ongoing performance feedback.
- A well-designed appraisal program requires clearly defined standards, feedback, and documentation that are applied consistently among all employees.
- Job expectations must be clearly stated.
- Elements of a formal appraisal should be based on an organization's mission statement, the job description, and the performance standards.
- Performance standards should be specific, measurable, realistic, and relevant to the job description.
- An employee's performance, not his or her ability, should be rated.
- Selection of a rating method depends on the purpose of the appraisal, the work environment, the skills of the employee, and the management style of the manager(s).

本书版权归John Wiley & Sons Inc.所有

- Self-appraisals may provide a different perspective of the employee's performance and a better understanding of obstacles that may impede performance.
- Peer-to-peer and 360-degree evaluations, if performed honestly, sincerely, and anonymously, may provide the employee with insight into his or her work relationships and performance. This assumes that all employees have received exposure to and training for the correct ways to deliver performance feedback.
- Preappraisal preparation by employees and managers is essential for a successful performance appraisal interview.
- Based on multiple "check-ins" with the employee during the year, performance appraisals should discuss progress with improvements throughout the year. A scheduled annual performance appraisal should hold no surprises for the employee and should not be punitive.
- The performance appraisal process should be motivating and should encourage feedback.
- If behavior modification is needed, focus on how you and your employee can work together to create a positive outcome.
- The employee should set at least four realistic goals for the coming year. Informal periodic checks on the employee's progress should occur throughout the year.
- Individuals performing appraisals should be given training and review the do's and don'ts of conducting appraisals to sharpen their skills in executing a successful interview.
- The appraisal process can and should be a form of career development.
- A manager can become a mentor and a positive force in an employee's career development. This relationship implies a more informal process that includes communication and assessments with the employee throughout the year.
- Appropriate behaviors may be reinforced with positive consequences.
- Recognizing accomplishments is a powerful way to motivate.
- A manager should provide examples of poor performance, if applicable, and the consequences of an unsatisfactory behavior.
- A manager should not overreact if an employee has an emotional outburst during an interview.
- A manager should encourage the employee to seek assistance from the employee assistance program, if available.
- Documentation and confidentiality are essential components of any performance appraisal program.
- A manager should identify ways to help an employee attain a higher level of performance.
- A successful appraisal program recognizes employees as the most valuable resource of an organization.
- Regulatory requirements indicate employee competency should be assessed semiannually the first year of employment and annually thereafter.
- Employee competency should be assessed whenever a change in test method or instrumentation occurs.
- Ongoing training and education are necessary to maintain and enhance employee competency.
- Thorough documentation of employee competency must be maintained for inspection by accreditation agencies.
- Competent employees are the foundation for the quality and success of any laboratory.

GLOSSARY

360-degree evaluation Multilevel assessment adopted by AT&T, IBM, and other Fortune 500 corporations. May be used to identify how a manager is viewed by his or her supervisor, peers, subordinates, and customers. Full-circle feedback.

Americans with Disabilities Act (ADA) Prohibits discrimination against qualified disabled individuals. Applies to institutions with 15 or more employees.

Appraisal type Formal and informal appraisals, self-appraisals, peer-to-peer appraisals, 360-degree appraisals.

Behaviorally anchored rating scale (BARS) Assessment of performance requiring input from other observers based on how employees behaved in a given situation.

Checklist adjectives evaluation At least three adjectives (e.g., aggressive, articulate, meticulous) from a checklist are selected to describe desirable as well as undesirable characteristics of an employee.

Clinical and Laboratory Standards Institute (CLSI) A voluntary national organization that issues guidelines for laboratory practices. Formerly the National Committee for Clinical Laboratory Standards (NCCLS).

Clinical Laboratory Improvement Amendments (CLIA) '88 An act passed by Congress in 1988 that requires an objective system to document competency of employees performing testing on patient specimens.

COLA Inc. Formerly the Commission on Office Laboratory Accreditation, a national nonprofit physician-directed organization that provides continuing medical education programs, accreditation standards, and accreditation of physician office laboratories.

College of American Pathologists (CAP) A medical society of board-certified pathologists that provides proficiency testing samples, continuing medical education programs, accreditation standards, and accreditation of pathology and laboratory services.

本书版权归John Wiley & Sons Inc.所有

Competency Ability to do a job correctly and safely and to recognize and solve minor problems without assistance.

Criterion Standard for judging task performance.

Critical incident evaluation Written notations of exceptional performance summarized in the performance appraisal.

Digital scanned slide/microscopy The digitization of optically scanned anatomical and/or clinical pathology slides (scanning) and the viewing of these scans via specialized computer software at a resolution and clarity like that seen using conventional microscopy.

Employee assistance program Psychological assessment and brief treatment; considered an employee benefit.

Equal Employment Opportunity Commission of 1972 Enforces the ADA.

Forced distribution Evaluation system in which the rater distributes a certain percentage of employees into each of several categories (e.g., outstanding, above average, average, below average, unsatisfactory).

Graphic rating scales System for rating a quality or characteristic by choosing a point along a horizontal axis. The scale may have discrete points (1 to 5, corresponding to excellent, good, fair, poor, unacceptable) or be continuous.

Halo effect Scenario in which the appraiser gives all employees an acceptable rating, regardless of their performance. When an employee is outstanding in one area, an evaluator ignores performance problems in other areas. Opposite of the pitchfork effect.

Interview A two-way discussion between employee and manager about the employee's performance (inter, "between"; view, "look").

The Joint Commission (TJC) An independent, not-for-profit organization that develops accreditation standards and accredits healthcare organizations.

Key results area An aspect of a job on which employees must concentrate time and attention to ensure that they achieve the goal for that job. This forces the manager to focus only on those activities that add value. Although it is motivational, staff may be slow to accept it.

Narrative rating An evaluation that includes concise, specific illustrations. It is easy to construct but subjective; this makes it difficult to compare employees' ratings.

Norms Informal behaviors that are generally acceptable in a workplace.

Performance appraisal A planned, formal, and periodic management activity in which an employee's on-the-job behavior is evaluated to enable salary and promotion decisions, change an employee's behavior, determine competence, improve work skills, identify training needs, and determine progress toward goals and career development.

Performance standards Defined performance expectations that are specific and measurable.

Pitchfork effect Poor performance in an isolated instance that adversely affects an employee's assessment. Opposite of the halo effect.

Ranking system A system that evaluates employees based on comparison with their peers (e.g., paired comparison or person-to-person comparison). This system does not allow all employees to be ranked as excellent, even if all employees have an excellent work performance.

Rating system A system that compares employee performance to a set of criteria and produces either a number or a letter grade that represents the employee's level of performance (e.g., graphic scale, free form, critical incident, behaviorally anchored scale, checklist of adjectives, forced choice, or distribution). Allows everyone to be rated highly, if they deserve it.

Results-based evaluations (RBEs) Evaluations performed by managers who focus on attainment of specific, measurable results.

SMART objectives Objectives that are specific, measurable, achievable, relevant, and timely.

Virtual slide Digital image created when glass slides are digitally scanned in their entirety to provide a high-resolution digital image using a digital scanning system. They can be viewed on a computer screen by running image management software on a standard web browser and can be assessed in exactly the same way as on a microscope.

Whole-slide imaging Imaging technique developed in 1999 that provides the opportunity to scan a complete microscope slide to create a single high-resolution digital file that can be viewed on a computer screen.

REFERENCES

1. **Neal JE**. 2001. *The #1 Guide to Performance Appraisals*. Neal Publications, Inc, Perrysburg, OH.

2. **Margrave A**, **Gorden R**. 2001. *The Complete Idiot's Guide to Performance Appraisals*. Alpha Books, Indianapolis, IN.

3. **Swan WS**. 1991. *How to Do a Superior Performance Appraisal*. John Wiley and Sons, New York, NY.

4. **Wolfgang JW**, **Wolfgang KE**. 1998. Standards and appraisals of laboratory performance, p 245–254. *In* Snyder JR, Wilkinson DW (ed), *Management in Laboratory Medicine*, 3rd ed. Lippincott, Philadelphia, PA.

5. **Cappelli P**, **Tavis A**. October 2016. The performance management revolution. *Harv Bus Rev*.

6. **Futcher R**. 2021. Performance appraisals, there is light at the end of the tunnel. https://www.russellfutcher.com/new-blog/2021/6/4/why-your-annual-performance-appraisal-was-probably-an-insult. Accessed 12 August 2022.

7. **Jenkins M**, **Coens T**. 2000. *Abolishing Performance Appraisals: Why They Backfire and What to Do Instead*, p 6. Berrett-Koehler Publishers, Inc, San Francisco, CA.

8. **Markle GL**. 2000. *Catalytic Coaching: The End of the Performance Review*. Greenwood Publishing Group, Westport, CT.

9. **Nelson B**, **Economy P**. 2010. Performance evaluations: not necessarily a waste of time, p 153–165. *In* Nelson B, Economy P (ed), *Managing for Dummies*. IDG Books Worldwide, Inc., Foster City, CA.

本书版权归John Wiley & Sons Inc.所有

10. Garcia LS. 1995. *Tech Sample Management and Education No. MGM-6: Employee Performance Evaluations: Past Approaches and New Options*. American Society for Clinical Pathology, Chicago, IL.

11. Mankins MC, **Garton E**. 2017. *Time, Talent, Energy: Overcome Organizational Drag and Unleash your Team's Productive Power*. Harvard Business Review Press, Boston, MA.

12. Layland A, **Leena N**. 2017. Appraisals in healthcare. *People* **17**:218–220

13. Gonzalez A, **Cervoni C**, **Lochner M**, **Marangio J**, **Stanley C**, **Marriott S**. 2020. Supporting health care workers during the COVID-19 pandemic: mental health support initiatives and lessons learned from an academic medical center. *Psychol Trauma Theory Res Practice Policy* **12**(S1):S168–S170. https://psycnet.apa.org/fulltext/2020-43979-001.html. Accessed 12 August 2022.

14. Elder BL, **Sharp SE**. 2003. *Cumitech 39, Competency Assessment in the Clinical Microbiology Laboratory*. Coordinating ed, Sharp SE. ASM Press, Washington, DC.

15. Snyder JR. 1991. Assessing the legality of performance appraisals. *Clin Lab Manage Rev* **5**:483–486, 488–489.

16. Scotto D. 1999. Performance appraisals: more than just going through the motions. *MLO Med Lab Obs* **31**:38–43, 57.

17. College of American Pathologists. 2012. *Laboratory Accreditation Program Laboratory General Checklist, rev. July 31*. College of American Pathologists, Northfield, IL.

18. Pell AR. 1999. Evaluating team members' performance, p 269–284. *In* Pell AR (ed), *The Complete Idiot's Guide to Managing People*, 2nd ed. Alpha Books, Indianapolis, IN.

19. Garcia LS. 1989. *Tech Sample Management and Education No. MGM-2: The Development and Use of Performance Standards*. American Society for Clinical Pathology, Chicago, IL.

20. Day CM. 1991. A hard look at performance reviews. *MLO Med Lab Obs* **23**:61–62.

21. McKirchy K. 1998. *Powerful Performance Appraisals*. Career Press, Franklin Lakes, NJ.

22. Nigon DL. 2000. Managing people, p 63–105. *In* Nigon DL (ed), *Clinical Laboratory Management: Leadership Principles for the 21st Century*. McGraw-Hill, New York, NY.

23. Umiker WO. 1984. The performance review and planning session, p 208–215. *In* Umiker WO (ed), *The Effective Laboratory Supervisor*. Medical Economic Books, Oradell, NJ.

24. Snyder JR. 1987. *Tech Sample Management and Education No. MGM-4: Refocusing the Employee Performance Appraisal Process*. American Society for Clinical Pathology, Chicago, IL.

25. Neal JE. 2009. *Effective Phrases for Performance Appraisals: A Guide to Successful Evaluations*, 12th ed. Neal Publications, Inc, Perrysburg, OH.

26. Wakefield Research. 2018. New study uncovers major gap in employee and employer expectations for performance management and growth. https://www.reflektive.com/press-release/new-study-uncovers-major-gap-employee-employer-expectations-performance-management-growth/. Accessed 14 August 2022.

27. The Joint Commission. 1999. *2000–2001 Comprehensive Accreditation Manual for Pathology and Clinical Laboratory Services*. Joint Commission on Accreditation of Healthcare Organizations. Oakbrook Terrace, IL.

28. Clinical Laboratory Improvement Amendments. 31 October 1988. Clinical Laboratory Improvement Amendments. Public Law 100-578, 102 Stat. 2903-2915. 42 U.S.C. 263a.

29. Code of Federal Regulations. 1992. Clinical Laboratory Improvement Amendments of 1988, final rule. *Fed Regist* **42**:CFR 493.

30. Decker PJ, **Strader MK**, **Wise RJ**. 1997. Beyond JCAHO: using competency models to improve healthcare organizations. Part I. *Hosp Top* **75**:23–28.

31. Commission on Office Laboratory Accreditation. 2007. *Laboratory Accreditation Manual, rev. 9*. Commission on Office Laboratory Accreditation, Columbia, MD.

32. CLSI. 2009. *Training Verification for Laboratory Personnel; Approved Guideline*. CLSI document GP21-A3. CLSI, Wayne, PA.

33. Decker PJ, **Strader MK**, **Wise RJ**. 1997. Beyond JCAHO: using competency models to change healthcare organizations. Part 2: developing competence assessment systems. *Hosp Top* **75**:10–17.

34. McCarter YS, **Robinson A**. 1997. Competency assessment in clinical microbiology. *Clin Microbiol Newsl* **19**:97–101.

35. Vengelen-Tyler V. 2001. *Tech Sample Management and Education No. MGM-6: How to Improve Documentation of Staff Competency*. American Society for Clinical Pathology, Chicago, IL.

36. Schiffgens J, **Bush V**. 2001. A four-part approach to competency assessment. *Lab Med* **32**:431–435.

37. Haun DE, **Leach AP**, **Fink DF**, **Lipscomb G**. 2000. A better way to assess WBC differential counting skills. *Lab Med* **31**:329–333.

38. Kumar N, **Gupta R**, **Gupta S**. 2020. Whole slide imaging (WSI) in pathology: current perspectives and future directions. *J Digit Imaging* **33**:1034–1040.

39. The Joint Commission. 1998. *Age-Specific Competence*. Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, IL.

40. Kirven DR. 2003. Age-specific techniques in phlebotomy competency: understanding and incorporating age-specific competence in evaluating the phlebotomist's performance. *Adv Med Lab Prof* **15**:11–17.

41. DelPo A. 2005. *The Performance Appraisal Handbook*. Nolo, Berkeley, CA.

42. Sharp S. 2001. Initial training verification and competency assessment in the clinical microbiology laboratory. *Clin Microbiol Newsl* **23**:79–81.

43. Howanitz PJ, **Valenstein PN**, **Fine G**. 2000. Employee competence and performance-based assessment: a College of American Pathologists Q-probes study of laboratory personnel in 522 institutions. *Arch Pathol Lab Med* **124**:195–202.

44. Decker PJ. 1999. The hidden competencies of healthcare: why self-esteem, accountability, and professionalism may affect hospital customer satisfaction scores. *Hosp Top* **77**:14–26.

45. Tziner A, Murphy KR, Cleveland JN, Roberts-Thompson GP. 2002. Relationships between attitudes toward organizations and performance appraisal systems and rating behavior. *Int J Selection Assess* **9**:226–239.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 13.1 Web-Based Software Products and Websites

Performance evaluation software provides real-time data regarding an employee's performance strengths and areas for improvement. These programs can be used to supply management with features designed to simplify and standardize the evaluation process. Consideration of software options should always include discussions with other actual customers currently using the program(s).

PERFORMANCE APPRAISAL SOFTWARE

SoftwareTestingHelp: Top 10 BEST employee performance evaluation software in 2023 (7 August 2022)

Extensive information comparing some of the best performance management systems

https://www.softwaretestinghelp.com/performance-evaluation-software/ (accessed 14 August 2022)

PERFORMANCE APPRAISAL WEBSITES

WorldatWork

http://www.worldatwork.org (accessed 14 August 2022)

Centers for Disease Control and Prevention

Competency guidelines for laboratory professionals

https://www.cdc.gov/csels/dls/competency-guidelines-laboratory-professionals.html (accessed 7 March 2023)

COMPETENCY ASSESSMENT PROGRAMS

College of American Pathologists

Competency assessment hub

https://learn.cap.org/lms/assessmentprogram (accessed 14 August 2022) Email: competency@cap.org

CAP Competency Assessment HUB

Pro courses

https://documents-cloud.cap.org/appdocs/learning/CompetencyAssessments/ContentPage/ProCourseListing_Aug2022.pdf (accessed 7 March 2023)

EMPLOYEE PERFORMANCE APPRAISAL FORMS

Sample forms

https://www.sampleforms.com/printable-employee-evaluation-form.html (accessed 14 August 2022)

Society for Human Resource Management

Employee performance appraisal form (including supervisory skills)

https://www.shrm.org/resourcesandtools/tools-and-samples/hr-forms/pages/performance-appraisal-with-supervisory-skills.aspx (accessed 7 March 2023)

Competency Assessment in the Clinical Microbiology Laboratory (2004)

https://journals.asm.org/doi/10.1128/CMR.17.3.681-694.2004 (accessed 7 March 2023)

SmartLabTools

Competency assessment resources (free templates)

https://www.smartlabtools.com/competency_assessment (accessed 7 March 2023)

PerformanceReviewsNet (2021)

Employee evaluation forms

https://performancereviews.net/employee-evaluation-form/ (accessed 7 March 2023)

CLINICAL LABORATORY JOB DESCRIPTIONS

University of New Mexico

Position classification description

https://jobdescriptions.unm.edu/detail.php?id=T0017 (accessed 14 August 2022)

Missouri State University, Office of Human Resources

Job description: 6412 medical technologist

https://www.missouristate.edu/Human/JobDescriptions/6412.htm#:~:text=The%20Medical%20Technologist%20performs%20professional,patient%20specimens%20for%20medical%20diagnosis (accessed 14 August 2022)

University of Wisconsin, UW Health

Job description: Medical technologist

https://www.uwhealth.org/files-directory/position-descriptions/laboratory/lab.technologists/medical.technologist.510011.pdf (accessed 14 August 2022)

University of Wisconsin, UW Health

Job description: Medical technologist senior

https://www.uwhealth.org/files-directory/position-descriptions/laboratory/lab.technologists/medical.technologist.senior.510013.pdf (accessed 14 August 2022)

Indeed

Clinical laboratory technologist: definition, duties, and skills

https://www.indeed.com/career-advice/finding-a-job/clinical-laboratory-technologist (accessed 14 August 2022)

Oroville Hospital

Job description for clinical laboratory technician

https://www.orovillehospital.com/media/file/Clinical%20Laboratory%20TechnicianJob%20Description.pdf (accessed 14 August 2022)

Central Virginia Family Physicians

Medical laboratory technician: job description

https://www.cvfp.net/wp-content/uploads/2016/11/Medical_Laboratory_Technician_2-16.pdf (accessed 14 August 2022)

本书版权归John Wiley & Sons Inc.所有

14

Staffing and Scheduling

Patti Medvescek

Introduction
Laboratory Personnel: Current Dynamics Affecting Staffing
Labor Shortage • Business Need • Increasing Opportunities for Medical Technologists
Personnel Requirements
Education • Training and Competence Assessment • Functional Definitions • Generalist versus Specialist
Laboratory Staffing
Staffing Requirements • Basis for Determination: Workload Recording
Staff Scheduling
Key Success Factors • Metrics for Success • Alternatives • Special Considerations • Flexible Staffing
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES
APPENDIX

OBJECTIVES

To explain the dynamics of staffing and scheduling laboratory personnel with respect to current labor trends and business requirements

To describe the personnel classifications as determined by governing bodies, accreditation agencies, and specific laboratory needs

To compare and contrast traditional versus alternative staffing plans, using personnel classification and qualification and service requirements

To describe key success factors for laboratory scheduling and metrics for effectiveness and efficiency

Creativity seems to emerge from multiple experiences, coupled with a well-supported development of personal resources, including a sense of freedom to venture beyond the known.

Loris Malaguzzi

The American Hospital Association reports that labor costs account for more than 50% of hospitals' total expenses (1). This statement includes the clinical laboratory. The education and experience required of the laboratory staff as well as staff scheduling models can optimize laboratory operations to reduce total labor expenses through skill mix strategies including utilization of contract staffing. Failure to recognize the impact of staffing and scheduling might diminish services provided and negatively affect the operating budget. Laboratory managers must understand the current and future dynamics that influence staff availability and must be aware of scheduling opportunities to provide efficient and effective laboratory operations.

Laboratory Personnel: Current Dynamics Affecting Staffing

Labor Shortage

Many organizations, including the American Society for Clinical Laboratory Science (2), have reported on the shortage of clinical laboratory scientists. Stephen Roper stated in the 26 July 2022 *Clinical Laboratory News,* "The clinical laboratory workforce has been battling personnel shortages long before the pandemic. The root of this problem is multifactorial, but it boils down to simple supply and demand. In the last 20 years, there have been fewer graduates from clinical lab education programs due to school closings. At the same time, the need for lab

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch14.

本书版权归John Wiley & Sons Inc.所有

services is increasing because of expanded insurance coverage and an aging population in need of medical care" (3).

A 2019 Bureau of Labor Statistics report stated that the need for clinical laboratory professionals will increase. "Employment of medical laboratory technologists and technicians is expected to grow by 7 percent between 2019 and 2029, about as fast as the average for all occupations. In addition, about 25,600 openings for clinical laboratory technologists and technicians are projected each year, on average, over the next decade" (3).

Today, the laboratory manager must be aware of the labor pool available in the community as well as the tenure of laboratory staff to predict potential shortages. The availability of trained individuals to perform laboratory testing is and should be a concern for laboratory managers. The creative staffing and scheduling needed to reduce staffing requirements are as important today as in the late 1990s to lessen the impact of this shortage. In addition, the absolute need to maintain efficiency in labor utilization to control costs is increasingly apparent based on the potential and future changes in reimbursement based on patient satisfaction and patient outcomes. The opportunity to fill in schedules with contract (traveler) positions must be assessed in terms of cost/benefit. Coupled with the impact of a global pandemic on healthcare, the need for optimizing staff is essential.

Business Need

The *Occupational Outlook Handbook* Job Outlook reports, "An increase in the population of older adults is expected to lead to a greater need for diagnosing medical conditions, such as cancer or type 2 diabetes, through laboratory procedures. Prenatal testing for various genetic conditions is also increasingly common. Clinical laboratory technologists and technicians will be in demand to use and maintain equipment needed for diagnosis and treatment. New, increasingly powerful diagnostic tests will encourage additional testing and spur employment. On the other hand, research and development efforts targeted at simplifying routine testing procedures may enhance the ability of non-laboratory personnel, physicians and patients, in particular, to perform tests now done in laboratories" (4). As hospitals (and laboratories) continue their evolution from healthcare providers to businesses providing healthcare services, laboratory managers are faced with the challenges of achieving a balance between skill levels of staff and scheduling staff to maintain services while reducing costs. How the laboratory interacts with other ancillary and hospital departments becomes important as cost sharing, cost savings, and point-of-care testing are integrated into the hospital.

Increasing Opportunities for Medical Technologists

The Bureau of Labor Statistics, in the *Occupational Outlook Handbook*, lists related fields in chemistry, materials science, and veterinary medicine. Also available to laboratory personnel are positions in manufacturing and industry, including sales, technical support, and research and development. Clearly, the labor shortage, the increased need for trained personnel, the availability of jobs in non-healthcare settings, and the barriers for entry into the field (perceived low salary and schedule demands) mandate the need for effective staffing and scheduling in the clinical laboratory to make the best use of and retain available talent.

Personnel Requirements

Education

Medical and clinical laboratory technologists generally have a bachelor's degree in medical technology or one of the life sciences or a combination of formal training and work experience. Technicians generally have either an associate's degree or certification from a hospital vocational or technical school. Several programs provide certifications for technologists and technicians or training program guidelines, including the American Society for Clinical Pathology (ASCP), the American Society of Clinical Laboratory Scientists (ASCLS), the National Credentialing Agency, and the Clinical and Laboratory Standards Institute (CLSI), formerly the National Committee for Clinical Laboratory Standards (NCCLS).

The basic requirements for personnel to perform testing in a clinical laboratory are proscribed in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) (5). Tests are grouped by complexity (as defined within the Code of Federal Regulations Sec. 493), with specific licensure, education, or experience requirements for each complexity model. The degree required for testing personnel varies and includes doctors of medicine or osteopathy; doctoral, master's, or bachelor's degrees; associate degrees; or high school diplomas. The common denominator is documented training for each individual performing laboratory testing, based on the complexity of the tests performed. The credentialing options (for example, Bachelor of Science degree in medical technology or chemistry, or high school diploma plus military training) provide the laboratory manager with flexibility in hiring decisions and scheduling. This flexibility can be defined in terms of ratios of technologists, technicians, and employees with a high school education plus training. The College of American Pathologists (CAP) and other organizations with deemed status under CLIA '88 to provide accreditation programs for clinical laboratories require that "all testing personnel meet CLIA '88 requirements" (6).

If the overall laboratory staff increases, the ratio of technicians to technologists may change in favor of technicians and those trained on the job. As staffing decreases, more technologists (qualifying as technical supervisor) are needed to ensure that qualified personnel are available to perform all services over all shifts.

本书版权归John Wiley & Sons Inc.所有

Training and Competence Assessment

Accreditation processes address the need for continuous training for laboratory staff. In the 2022 General Checklist, the CAP states that there should be "a functional continuing clinical laboratory education program adequate to meet the needs of all personnel" and that "the competency of each person to perform his/her assigned duties is assessed" (6).

Each technologist or technician must be competent to perform laboratory tests based on the specific policies and procedures of the laboratory. Training and competence must be documented within personnel records. In addition, on-the-job training may be integrated into the laboratory for those with the minimum education required. Consideration should be given to on-the-job training, especially for laboratory assistants or phlebotomy staff, for job improvement and promotion. As the labor pool of skilled employees decreases, developing a pool from within provides the laboratory manager with additional resources to staff the laboratory. Employees who are trained and ready to perform a variety of tests limit the negative impact of staff absence, leaves of absence, or open positions in the laboratory.

The ASCP, the American Society for Microbiology, the National Credentialing Agency, and the Clinical Laboratory Management Association, among others, provide continuing education opportunities through journal reviews, educational programs, and meeting seminars.

Functional Definitions

For purposes of this text, several terms are discussed within the context of staffing and scheduling in the laboratory:

- *Laboratory size* is identified due to the differing needs for the laboratory based on physical limitations (multiple locations, floors, laboratories requiring additional personnel to efficiently perform testing). Small laboratories occupying less square footage may require fewer personnel if a generalist can cover all the areas.
- *Laboratory location*, also a variable, should be considered. For example, for a hospital laboratory, proximity to high-use areas, such as the emergency room (ER) or intensive care unit, will lessen the time required for transportation of personnel services between these areas and the laboratory. Decentralized services will affect staffing requirements. Staffing STAT laboratories, outpatient facilities, and nursing unit stations requires additional personnel. The benefit of decentralized services is improved turnaround time for direct services; the cost is trained personnel to staff the areas.
- *Laboratory test menus* are a factor in determining staffing patterns, based on the complexity of testing performed. A generalist model may be appropriate for a hospital or physician office laboratory (POL) that refers microbiology identification and susceptibility testing or blood bank antibody identification; the specialist model may be required for laboratories, regardless of size, that provide a tertiary level of service.
- *Laboratory service levels* include activities defined by process or contract. These may include specimen collection on- and off-site, POL support, reporting procedures, and other support provided by the laboratory to one or more facilities.
- *Flexible staffing* involves staffing to workload demand by assessing workload on a shift-by-shift basis, routinely canceling or floating staff based on workload.
- *Fixed staffing* involves a fixed, budgeted number of full-time equivalents (FTEs) projected to complete the anticipated workload.

Generalist versus Specialist

The staffing model widely used 30 years ago was based on specialists for every discipline in the laboratory. Labor-saving instruments and computerization have changed the testing process in the laboratory, allowing ease of test performance. This opens the opportunity to employ a generalist model in the laboratory. Generalists can be cross-trained for all laboratory sections. Cross-training can be defined for staffing purposes as training an individual to perform testing in more than one functional area of the laboratory. Traditionally, medical technologists were assigned to a specific section, e.g., hematology or chemistry, and their competency was assessed only for those tests performed in that area. By training personnel to perform testing in multiple areas of the laboratory, the laboratory manager has the skill mix available to assign individuals where the need is greatest at the time. Cross-training in multiple areas of the laboratory requires more resource allocation for competency assessment. The cost of increasing breadth of training must be balanced by efficiencies gained from cross-training. Cross-training generalists, however, may not be advantageous for very complex facilities for all areas of testing. Esoteric or highly specialized disciplines need the depth of knowledge that a specialist provides. The laboratory manager can employ a hybrid model by identifying those tasks common to all areas of the laboratory and training all qualified staff members. Based on the experience of the author, the pros and cons of generalist versus specialist are shown in Table 14.1.

In addition to the generalist versus specialist model, the laboratory manager should review career levels within each job function. Career advancement in medical technology can follow the administrative track (to laboratory supervision) or the technical specialist's track, e.g., senior technologists. Having two career tracks does provide options for laboratory employees to stay in the laboratory

本书版权归John Wiley & Sons Inc.所有

Table 14.1 Generalist versus specialist staffing models[a]

Model	Pros	Cons
Generalist	Staffing flexibility Entry level opportunities Breadth of knowledge	Increased resource allocation to maintain and document staff competency Entry level, as staff gain experience in tenure Lack of depth
Specialist	Depth of knowledge Career ladder opportunity	Narrow base of experience Limited flexibility in scheduling

[a]Based on the author's experience supporting a multi-hospital system.

Table 14.2 Staffing ratio: costs and benefits[a]

Staff	Cost	Benefit
Technologists	Expense and availability	Expertise in testing methods Ability to analyze and solve problems
Technicians	Expertise may be insufficient to review or troubleshoot test results	Less expensive
On-job trained	Training program preparation and implementation	Resource supply, lower labor cost

[a]For purposes of this illustration, Technologists will typically have a BS degree and accreditation as a Clinical Laboratory Specialist/MT(SCAP). Technicians are trained as medical laboratory technicians, usually with an associate's degree. On-the-job trained individuals have high school degrees and supervision/training in the laboratory. (See CFR Title 42/ChapterIV/Subchapter G/Part 493 [https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M/subject-group-ECFR2640b368593bdb0/section-493.1489, accessed 6 October 2023], detailing the requirements for personnel based on complexity of testing provided.)

through job enrichment and job enhancement. When staffing is adequate to accommodate multiple levels of job categories, the potential exists to reduce turnover and provide additional resources for problem resolution, technical consultation, and staff education.

If cost savings are needed in the laboratory and labor accounts for a large percentage of the laboratory budget, then changing the skill mix of the staff is one way to achieve cost savings. However, the optimal mix of assistants, technicians, and technologists (specialists and generalists) should be specific for each facility based on the functional definitions of the laboratory. Once the CLIA '88 requirements are satisfied for testing personnel, it is up to the laboratory manager and director to determine the proper mix. Cost/benefit analysis can assist in determining this mix, as shown in Table 14.2.

Laboratory Staffing

Staffing Requirements

The laboratory manager must assess the needs of the laboratory to determine the number of employees needed as well as the mix of expertise, training, or credentials of technical staff. The following are elements within the laboratory that should be addressed.

Test mix. A large test menu, including moderately and highly complex tests, requires a different group of technical staff than a laboratory performing mostly routine testing on automated analyzers. Specialty areas in microbiology, surgical pathology or cytology, and blood bank also require special consideration.

Hours of operation. A full-service laboratory supporting an ER and/or intensive care units requires a different pattern than an outpatient laboratory or POL providing services Monday to Friday for one shift. Staff must be available to support the emergency room and critical care units, at least for those tests that must be available as STAT tests at all times. The STAT test menu is an important tool for the laboratory manager to ensure adequate staffing at all times to meet the expectations for services provided.

Supervision. The requirements for on-site technical supervision in CLIA '88 mandate the need for technologists in addition to technicians on off shifts, weekends, and holidays (5).

Service levels. Turnaround time, phlebotomy, results reporting, and sequential testing are all variables to consider when staffing the laboratory. An outpatient laboratory may provide all test results by the next day, allowing for a smaller staff to perform specimen collection during the day, with batch testing performed in the early evening. A full-service laboratory performing tests for the ER will require testing personnel 24 hours/day to perform a STAT test menu with turnaround times within minutes. Computerized result reporting eliminates the need for laboratory assistants to hand-deliver test results. Automatic sequential or cascade testing relieves clerical or technical staff of contacting physicians with results and/or waiting for additional test requests. The laboratory manager should understand the costs/benefits of utilizing a reference laboratory for routine testing, if the desired service level can be maintained, based on the expectations set by the medical staff and hospital administration.

Services supported. Laboratories that support an emergency room, transplant programs, cardiovascular surgical programs, and clinics, to name a few, could have different minimum staffing requirements than a general acute-care suburban facility. The trauma center designations (Levels 1 through IV) require 24/7 coverage at minimum to provide evaluation, stabilization, and diagnostic capabilities for patients, which includes comprehensive laboratory services (7).

本书版权归John Wiley & Sons Inc.所有

Productivity levels. The author has based productivity goals on a "traditional" 80% productivity measure. The key, however, is to know how to define the term "productivity," including the metrics to measure productivity. For example, if the amount of time available to work is used as maximum opportunity, then the 8-hour day is actually 7 hours (assuming 1 hour for lunch and breaks); i.e., 100% productivity of available work time is 87% of total worked time. Productivity is also a useful indicator to determine optimum staffing in conjunction with minimum staffing. Few laboratories can afford to hire enough personnel to staff the laboratory for maximum workload levels. Similarly, few laboratories can afford the issues (increased turnaround times, additional overtime expense) inherent in minimum staffing levels, when productivity approaches 100% as workload increases. The creative manager will staff for the typical workload day, with additional personnel available to call in when workload exceeds projections. This flexibility is the primary advantage to part-time, flextime, and cross-trained individuals.

Productivity levels are also based on the unit of measure used, typically the number of billable tests. However, the mix of billable tests (inpatient versus outpatient, STAT versus routine, increased non-billable components) can impact productivity comparisons. Assessing staffing needs daily, or even on a shift-by-shift basis, ensures tighter control of labor expense, as long as trained staff is available to "flex up" or staff is willing to "flex down" as volume changes. Both are key components of the flex (variable) staffing model. In addition, predicting when volumes will increase or decrease allows the laboratory manager to effectively predict shifts of higher or lower volume and schedule accordingly to mitigate the impact of a variable staffing model. For example, correlating high test volume with surgery schedules or low test volume with community events can provide the basis for staff schedules that meet but do not exceed the workload.

Basis for Determination: Workload Recording

Some method should be used to objectively document the amount of "work" performed by the laboratory. The units of work are factored by the hours required to perform the work to determine productivity. The Laboratory Management Index Program (LMIP) is one program that provides benchmarks for productivity, utilization, and cost-effectiveness. In 1982, the LMIP replaced the CAP Workload Recording Method. LMIP is based on a standardized chart of accounts that more accurately identifies all costs, and from which have been developed a series of ratios to measure management performance (8). The standard billable test (SBT) is the primary unit of measure for LMIP. The SBT is a method of standardizing test counts and eliminates billing, accounting, and interpretation variations to ensure that valid comparisons are created.

There are other productivity measurement tools as well, such as proprietary external comparative databases that measure labor productivity (primarily) for acute-care hospitals, including the laboratory. Productivity is typically reported based on hours worked or paid per unit of measure (as defined in the database), adjusted days, or adjusted discharges. The key to workload recording is to determine the basis for calculation, while reducing the variables that can affect the comparisons and limiting the exceptions that will skew performance. The key to productivity comparison is understanding the variables among laboratories, including outpatient volumes, services supported, overall size and scope of the laboratory, and availability of alternative testing sites. If the laboratory manager chooses to engage in an external comparison for productivity measurement, several key factors must be considered. The measurement tool must be updated as new tests are added. The sample size of participants must be statistically valid and should allow for comparison with other laboratories of similar volumes and/or test mixes.

Workload recording is a valuable tool used to assess (and justify) staffing levels; however, the laboratory manager must understand the information that is provided and must ensure that the comparisons used are valid. When using a productivity tool, the definition of the workload recording unit must be established. The worked hours that are included must be comparable. For example, if some participants in the comparison group record only direct worked hours (excluding business leave, orientation, or meeting time) while others include all productive hours, then the results will be skewed in favor of the labs reporting only direct hours. Counting all analytes tested versus counting panels reported can result in one lab appearing very productive in comparison to labs that only report panels. Understanding the database definitions of the productivity reporting tool is key to obtaining relevant information. Interpreting the comparison results requires an understanding of the seasonality of test volumes when reviewing an annual report. Productivity reports are more directional (you use more staff per test) than absolute (you use 5.4 more FTEs per test) and typically require additional research to obtain specific staffing requirements.

The laboratory manager and director should be informed about projected patient volumes. If inpatient volumes are declining, staff may be downsized, despite an increasing outpatient volume. It is critical to understand the resource requirements for each patient "sector" and to justify staffing requirements via documentation of workload and efficiency. Retrospective data review of test volumes, correlating to surgery schedules, for example, provides the laboratory manager with a template for days off and vacation time requests.

本书版权归John Wiley & Sons Inc.所有

Staff Scheduling

Once the staffing mix has been developed and implemented, employees must be assigned to their work schedules. To schedule staff effectively, the laboratory manager must understand the needs of the laboratory, hours of operation, and the staff required versus the needs of the employees, for whom a work-life balance is becoming more important. The key, in the author's experience, involves open and frequent communication about operational needs along with an understanding of employee preferences. When the laboratory manager can include employees in the scheduling process, individual needs can be considered, as long as business needs are met. Some facilities have implemented self-scheduling. Following scheduling guidelines for skill level and number of shifts, among other factors, employees select their own schedules, based on their preferences. Self-scheduling is available on a first-come, first-served basis. If self-scheduling is not available, at minimum the laboratory manager should utilize employee-driven methods for scheduling shifts, including the opportunity for same-skill employees to trade shifts with approval.

The issue of work-life balance continues to be the subject of numerous articles. The AACC reported on its survey of laboratory professionals, "A sizable minority (39.0%) reported that quality of work-life balance was fair, compared with excellent (6.7%), good (34.2%), or poor (19.5%). Those reporting fair or poor work-life ratios also had much higher rates of burnout compared with those with excellent work-life balance" (9). By acknowledging and addressing work-life balance, the laboratory manager can improve or increase staff retention while continuing to provide the services required of the laboratory.

Key Success Factors

The laboratory manager should not only understand the factors that are critical to the success of the laboratory but also be able to demonstrate or document these key areas. For a department or cost center, two key success factors are financial performance and quality assurance. When reviewing staffing and scheduling, labor costs can be used to target areas of opportunity for improvement. The cost of overtime and turnover will affect overall person-hour and expense budgets. The achievement of targeted performance metrics influences the satisfaction of customers (e.g., physicians, patients).

Metrics for Success

Reporting efficiency. Laboratories have measured their reporting efficiency in terms of percent of tests reported within required or requested time frames. This metric is particularly important to those who take action on the test results, as treatment options and procedures depend on laboratory results. Reporting efficiency also can affect the financial performance of the hospital. When laboratory results are available and patient care is delivered efficiently, the patient length of stay may be decreased. For the reference laboratory, reporting efficiency to their customers is not only an indicator of performance; it may also be included in the contractual agreement, with financial considerations if metrics are not achieved.

Turnaround time. Turnaround time for results reporting includes all components of testing—specimen collection, processing, analysis and review, and reporting—and is an important indicator of effectiveness as well as efficiency. One component, specimen collection, can and should be monitored separately, whether the laboratory has responsibility for collecting patient samples or nursing units provide for specimen collection. The metric is the percent of tests collected within a time frame around the test request. For example, a hospital laboratory may report the percentage of 6 a.m. labs collected between 5:30 a.m. and 6:30 a.m. When the laboratory objective is to complete all timed blood drawn within 30 minutes of the requested time, the laboratory manager has to staff sufficient numbers of employees to meet this objective. And collecting samples at the time requested can improve the results of the tests requested. The importance of the timed lab collection is based on one or more of several factors. Some laboratory tests must be drawn at a certain time after (or before) administration of medication.

Productivity measurements. The productivity of the laboratory is a function of the number of tests performed by the number of personnel working, or workload units per full-time equivalent. Not all tests performed are billed, and there must be a distinction between billed, billable (but not billed for whatever reason), and non-billable tests when comparing productivity to financial performance. This distinction is also important when contracting for reagent purchases so the correct quantity of reagents for tests performed is used for negotiation and contractual obligation. If the laboratory staff is unable to complete the billable tests within an acceptable percentage of all tests, inventory levels, pricing, and efficiency are all affected. It is important to note the impact of the non-billable tests. Examples include repeat testing based on laboratory protocol or repeats based on physician request. The volume of quality control (QC) testing should also be considered, for labor as well as supply utilization. If, for example, the laboratory runs tests as they are received, and the QC protocol requires QC testing for each run, this lab will require more resources than the laboratory that batches tests. The best solution is to batch when appropriate as long as expected result turnaround times are met.

本书版权归John Wiley & Sons Inc.所有

Impact on staff. The implementation of productivity measurements can affect the laboratory staff. Productivity measures are an objective, quantitative means of reviewing performance but may be perceived as changing the workplace from a laboratory to an assembly line, where productivity is the only indicator of laboratory success. By including quality indicators such as proficiency surveys of performance in laboratory metrics, the laboratory manager can emphasize the importance of quality as well as productivity.

Scheduling processes. At a minimum, the manual schedule is prepared for the staff in advance. Scheduling software programs are available that include parameters for skills and training. The need for computerized scheduling is dictated in part by the size of the laboratory staff and the time available to devote to maintaining a manual versus a computerized system. Laboratory managers should examine the time required to prepare, distribute, post, and amend manual schedules and compare the labor intensity with the cost and implementation of a computerized process.

A basic template (Table 14.3) uses annual budgeted volumes and targeted productivity hours per test to project staffing needs by shift. Including the volume changes driven by seasonality or by day of week variances provides a more definitive schedule for the laboratory. Skill mix and staff experience should also be considered. As volumes fluctuate from budget, adjustments can be made in the schedule to accommodate changes. Ultimately, the laboratory must be staffed with sufficient personnel trained for the areas in which testing is provided.

Alternatives

Automation. Automation in the clinical laboratory, once limited to larger facilities and reference laboratories, is now being considered in smaller hospital laboratories as a means to mitigate open technologist positions. With automation, the available staff are able to complete requested testing with fewer "hands on." The cost of the automation is recovered by the decrease in labor expense. Technology also provides consolidation of resources to a central location for results review/release or autorelease of results, ensuring that test results are available.

Outsourcing. Reference laboratories have in the past provided esoteric testing not usually done in clinical laboratories. With overnight testing and air couriers, reference laboratories have expanded their menus to include routine testing. Routine testing that can be performed by a reference laboratory that provides 24-hour turnaround time could include any test that is not part of the STAT grouping (tests that must be reported within specific time frames to maintain patient safety). For example, cholesterol levels are an important test that could be performed at the bedside, in the laboratory, or by a reference laboratory. The laboratory manager should understand the costs for each scenario, including labor, as well as the benefits of in-house versus referral testing to determine the best course of action. The laboratory manager is challenged with deciding which tests to send out versus perform in-house, based on cost per test as well as service levels provided. For some laboratories with minimal test volumes, the ability to bill for tests performed must be also considered. The incremental opportunity for additional tests may justify the additional costs for technologists or equipment.

Opportunity cost and benefit. The laboratory manager should consider the impact of staffing decisions on the facility or physician using the laboratory. The manager should also consider the opportunity to combine job functions across departmental lines when feasible to take full advantage of the benefits provided. For example, locating the phlebotomy staff on nursing units provides efficiency for the laboratory in less travel time to the patient and also provides nursing units with ancillary personnel trained to provide defined levels of patient care. In some facilities, nursing services have the responsibility for specimen collection, utilizing their RN staff or training patient care assistants for phlebotomy.

Creative scheduling. Creative scheduling includes opportunities for job sharing, flextime, part-time, telecommuting, and self-directed teams (Table 14.4). Similarly skilled and trained employees can elect to share a position. This often decreases fringe benefit costs while providing equal hours worked. Flexible scheduling, based on employee need or request, can result in increased employee satisfaction, reducing turnover and poor performance. Telecommuting for specific positions such as medical transcription reduces space requirements for the laboratory, may enhance work performance, and provides an additional resource of experienced employees. Using self-directed teams reduces the time demands on the laboratory manager while providing job enrichment and satisfaction. Scheduling employees in nontraditional shifts (e.g., 10 a.m. to 6:30 p.m.) or four 10-hour days may provide work hours needed by the laboratory while meeting personal needs of the staff. Part-time employees can also provide additional resources for staff coverage in emergencies. The author recommended 20-hour coverage in one laboratory, from 4 a.m. to midnight, staffed by two 10-hour shifts. Testing was limited between midnight and 4 a.m. to the critical test menu, with limited swing shift staffing available to perform routine instrument maintenance and STAT testing as needed. These techniques can be as effective for variable (flex) staffing as for the fixed staffing model.

本书版权归John Wiley & Sons Inc.所有

Table 14.3 Shift scheduling template[a]

Data required	Example						
Annual volume of tests	300,000						
Productivity target (hours per test)	0.12						
Shift length	8 hours						
Days of operation	7 days						
Seasonal variability	None						
Day of week variability	None						
When volume is constant by month and day of week	Mon	Tue	Wed	Thur	Fri	Sat	Sun
Input average volume per day (annual volume divided by 365)	822	822	822	822	822	822	822
Input total worked hours required	99	99	99	99	99	99	99
Divide total hours required by average shift length to calculate number of shifts required	12	12	12	12	12	12	12
Day shift @ 60%	7.4	7.4	7.4	7.4	7.4	7.4	7.4
Evening shift @ 30%	3.7	3.7	3.7	3.7	3.7	3.7	3.7
Night shift @ 10%	1.2	1.2	1.2	1.2	1.2	1.2	1.2

[a]Template created by the author to calculate shifts required based on testing volumes.

Table 14.4 Scheduling alternatives[a]

Alternative	Pros	Cons
Job sharing	Decreases benefit costs	Potential lack of continuity
Flexible schedules	Employee satisfaction	Must be administered consistently and in accordance with human resource policy
Part-time schedules	Increases pool of employees	Lack of continuity
Telecommuting	Reduces overhead requirements, employee satisfaction	Limited to specific jobs, cost to establish and maintain links to the laboratory
Self-directed teams	Employee satisfaction, reduces management hands-on time	Consistent application of policy

[a]Pros and cons are based on experience of the author managing multiple laboratory areas with continuous employee feedback.

Special Considerations

Inpatient testing requires a 24/7 response for patient testing with more specific criteria for emergency, intensive care, or surgical patients. These requirements may add staff to the laboratory roster. Outpatient testing may still include weekend hours but is more limited in hours of operation. The facility or laboratory may have specific customer satisfaction metrics for outpatient visits, including waiting time. Shared services (inpatient facilities and outpatient testing stations within one department) provide more flexibility for shared staffing and an increase in the pool of trained personnel available for coverage.

Flexible Staffing

More hospitals today are using a variable staffing method for hospital departments that can "flex to volume," including the laboratory. The premise is that FTEs are budgeted based on the volume projected and the variable workload target that has been established (via external benchmarks, history, minimum staffing or service line support, or some combination of these). When actual volume exceeds budgeted volume, budgeted hours increase to match. Conversely, when actual volumes are less than budget, hours are decreased. The challenge for laboratory managers is multidimensional: When volume is down, staff can be sent home or rescheduled. But when volume increases, is there a pool of laboratory staff to call on to support the increase? If fluctuations are "managed" on a daily basis, are employees dissatisfied by the reduction of hours? Because of the opportunities available to clinical laboratory staff in other industries, employee dissatisfaction could lead to employee turnover, without the needed influx of new technicians and technologists. The laboratory manager must carefully assess the impact of routinely canceling or rescheduling staff and balance labor utilization with labor resources. Working with hospital administration is a key for effectively managing both components.

本书版权归John Wiley & Sons Inc.所有

SUMMARY

Effective laboratory staffing and scheduling will have a positive impact on the laboratory as a service provider. Changes in the availability of skilled employees, in the way laboratories are operated as businesses (cost center versus revenue center), and in the regulatory environment all create challenges today for laboratory managers hoping to optimize human resource utilization. These challenges can be limited or eliminated by understanding workload patterns, using creative scheduling, and utilizing available personnel for optimum productivity.

KEY POINTS

- Personnel classification and qualifications for laboratory operations are detailed.
- Traditional scheduling methods are under review as the laboratory as a service provider evolves (or has evolved) into the laboratory as an integral part of the business of healthcare.
- A key to understanding the depth of opportunity within a laboratory is to recognize the base requirements and the incremental impact of creative scheduling, labor pool, and services provided.
- Staffing and scheduling are very dependent on the locale, the availability of technical staff, the practice patterns by physicians, the service lines offered by the healthcare facility, and patient expectations.
- Scheduling processes are reviewed to provide options and opportunities that meet the key success factors for the laboratory.
- Variable staffing is defined as staffing to workload volume using targeted (or budgeted) hours per unit of volume, with productivity reports comparing actual labor to flex budget labor.

GLOSSARY

Clinical and Laboratory Standards Institute (CLSI) Voluntary consensus standards–developing organization disseminating standards and guidelines to the healthcare community.

Contingency workforce Employees not defined as permanent or regular employees, usually assigned jobs based on short-term needs.

Full-time equivalent Forty hours worked per week.

Generalist One trained in multiple areas of the laboratory.

Laboratory supervisor Individual responsible for staffing and scheduling the laboratory.

Medical Technician Also known as clinical laboratory technician. A person with an associate's degree in medical laboratory technology (or equivalent).

Medical Technologist Also known as clinical laboratory scientist. A person with a bachelor's degree in medical technology or in a selected health science who has completed a 1-year practicum.

Outsourcing Contracting with consultants, reference laboratories, or other clinical laboratories to provide services.

Productivity measures Raw numbers or calculations that describe work performed relative to hours worked, tests billed, revenue generated, reagents used, etc.

Specialist A person trained and experienced in one specific laboratory discipline; formally, one who has a minimum of 5 years' experience in that discipline and has passed a qualifying examination for that discipline by an accepted accrediting organization.

REFERENCES

1. **American Hospital Association**. 2022. Massive growth in expenses and rising inflation fuel continued financial challenges for America's hospitals and health systems. https://www.aha.org/system/files/media/file/2022/04/2022-Hospital-Expenses-Increase-Report-One-Pager.pdf. Accessed 11 February 2023.

2. **American Society for Clinical Laboratory Science**. 2023. Addressing the clinical laboratory workforce shortage. https://ascls.org/addressing-the-clinical-laboratory-workforce-shortage/. Accessed 11 February 2023.

3. **Roper S.** 2022. Practical strategies for workplace woes. *Clinical Laboratory News*, July 26, 2022. https://www.aacc.org/cln/cln-daily/2022/practical-strategies-for-workforce-woes. Accessed 11 February 2023

4. **Bureau of Labor Statistics, U.S. Department of Labor**. 2022. *Occupational Outlook Handbook*, Medical and Clinical Laboratory Technologists and Technicians. http://www.bls.gov/ooh/healthcare/medical-and-clinical-laboratory-technologists-and-technicians.htm. Accessed 18 January 2023.

5. **Clinical Laboratory Improvement Amendments.** 2023. Title 42, Chapter IV, Subchapter G, Part 493—Laboratory Requirements. Code of Federal Regulations. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493. Accessed 6 October 2023.

6. **College of American Pathologists**. 2022. Laboratory general checklist. College of American Pathologists Laboratory Accreditation Program. Gen.54200, Gen.55450. CAP, Northfield, IL.

7. **American Trauma Society**. 2023. Trauma levels explained. www amtrauma.org/page/traumalevels. Accessed 9 February 2023.

8. **Reilly B**. 1993. LMIP (Laboratory Management Index Program): the next generation in productivity measurement. *MLO Med Lab Obs* **25**:42–49.

9. **AACC**. 2020. The highs and lows of clinical lab professionals. *CLNStat*.https://www.aacc.org/cln/cln-stat/2020/april/16/the-highs-and-lows-of-clinical-lab-professionals. Accessed 6 October 2023.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 14.1 Further Information

WEBSITES

American Medical Technologists
http://www.americanmedtech.org (accessed 9 February 2023)
10700 West Higgins, Suite 150
Rosemont, IL 60018
Tel: 847-823-5169 or 1-800-275-1268

American Society for Clinical Laboratory Sciences (ASCLS)
http://www.ascls.org (accessed 9 February 2023)
1861 International Drive, Suite 200
Tysons Corner, VA 22102
Tel: 571-748-3770

American Society for Clinical Pathology (ASCP)
http://www.ascp.org (accessed 9 February 2023)
33 West Monroe Street, Suite 1600
Chicago, IL 60603
Tel: 312-541-4999

American Society for Microbiology (ASM)
http://www.asm.org (accessed 9 February 2023)
1752 N Street, NW
Washington, DC 20036
Tel: 207-737-3600

Clinical and Laboratory Standards Institute
http://www.clsi.org (accessed 9 February 2023)
950 West Valley Road, Suite 2500
Wayne, PA 19087
Tel: 610-688-0100

Clinical Laboratory Management Association (CLMA)
http://www.clma.org (accessed 9 February 2023) transitioning to ASCP.org 12/2021
401 N. Michigan Avenue, Suite 2200
Chicago, IL 60611
Tel: 312-321-5111

College of American Pathologists (CAP)
http://www.cap.org (accessed 9 February 2023)
325 Waukegan Road
Northfield, IL 60093-2750
Tel: 1-800-323-4040

REGULATIONS

Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, 2012–13 Edition, Medical and Clinical Laboratory Technologists and Technicians
http://www.bls.gov/ooh/healthcare/medical-and-clinical-laboratory-technologists-and-technicians.htm (accessed 6 May 2012)

Clinical Laboratory Improvement Amendments
Public Law 100-578, Section 353
Public Health Service Act (42 U.S.C. 263a), 31 October 1988
https://www.cdc.gov/clia/about.html (accessed 6 October 2023)

本书版权归John Wiley & Sons Inc.所有

15

Introduction
Definition of a Team
Types and Classifications of Teams • Why Define "Team" So Precisely?
Guidelines for Choosing Whether To Have Teams
Common Purpose • Interdependent Tasks • Costs: a Cautionary Note
Group Process and Teams
Selecting Team Members
Task- and Process-Related Training
Leading Teams
General Ideas about Leadership: a Brief Review • Leadership in a Team Environment • Team Leader Selection
Goal Setting, Performance, and Rewards
Goal Setting and Performance • Goal Setting and Teams • Evaluating Teams and Team Members • Rewarding Team Members
Virtual Teams and Remote Work
Global Teams (a Special Case of Virtual Teams)
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES
APPENDIX

Teams, Team Process, and Team Building

James W. Bishop, Dow Scott, Stephanie Maynard-Patrick, and Ji-Yeon Seok

OBJECTIVES

To define what constitutes a team

To state why a precise definition of "team" is important

To explain the concept of group process within teams

To describe the situations in which teams can be productive and those in which they cannot

To define "task interdependence," the types of task interdependence, and their importance

To explain how task interdependence influences choices related to teams

To explain the basic concepts behind selecting team members

To explain the importance of team training, distinguish the differences between task-related training and team-related training, and explain the concept of team building

To list the types of leadership associated with teams and the advantages and disadvantages of each

To explain the importance of goals, both individual and team; to explain how team goals can be set and achieved

To explain how to evaluate team and team member performance and emphasize individual performance in terms of contribution to the team

To examine how virtual teams have evolved as result of the COVID-19 pandemic

To explore the special challenges of global teams

> *What sets apart high-performance teams … is the degree of commitment, particularly how deeply committed the members are to one another.*
>
> Jon R. Katzenbach and Douglas K. Smith

Teams can be found everywhere in organizations. Employees are placed in work teams, task forces, committees, quality improvement teams, safety teams, and a variety of other teams. Employees working together is nothing new. In fact, it is the very nature of organizations to put employees into groupings. However, managers, consultants, and academicians make distinctions between employees organized into groups and those who operate as teams. In fact, they point out numerous advantages that are derived

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch15.

本书版权归John Wiley & Sons Inc.所有

from teams. These advantages include increased individual performance, better-quality output, less absenteeism, improved employee engagement, reduced employee turnover, leaner organizational structures, and substantial improvements in production cycle time (1). In general, teams are considered an important ingredient of organizational success in the modern economy due to needs for rapid information exchange and response to customer demands (2), so much so that work groups regardless of their effectiveness have been renamed in most business lexicons as "teams."

On the other hand, virtually everyone has had negative experiences working in teams. Dysfunctional teams can have a negative impact on employee performance, retention, and morale. These dysfunctions include conflict among team members, social loafing, misdirected goals that satisfy members of the team but not the organization, and poor communication (3).

This chapter examines what is involved in creating effective teams, first by differentiating ineffective and effective teams and then by examining team processes, exploring how and when teams can contribute to a more effective organization, and discussing how to select and develop the best team members, develop effective team leadership, and motivate team performance. Finally, we examine some of the latest developments and challenges in teams, including virtual and global teams.

Definition of a Team

There are many definitions of the term "team." These include, but are not limited to (2):

- A small number of people with complementary skills who are committed to a common purpose and performance goals for which they hold themselves mutually accountable
- A group whose individual efforts result in a performance that is greater than the sum of those individual parts (4)
- Two or more people with different tasks who work together adaptively to achieve specified and shared goals
- A collective group of individuals who are interdependent in their tasks, who share responsibility for outcomes, who see themselves and who are seen by others as an intact social entity embedded in one or more larger social systems (for example, business unit or corporation), and who manage their relationships across organizational boundaries

The fundamental differences among teams, i.e., the level of effectiveness and quality of the relationships that team members have with each other, are discussed below. Implicit in each definition is the idea of both individual and collective accountability. Individuals can be rewarded or taken to task for both the team's results and their own contributions to the results.

Types and Classifications of Teams

There are various ways to categorize teams. Based on how members allocate their time, teams can be full-time or part-time. Teams can be permanent or temporary. Teams can be highly effective with very committed members or simply a collection of individuals whose work together contributes little to their overall productivity. From a functional perspective, teams can be classified into three types (2).

- Teams that make recommendations include task forces, project teams, and audit, quality, or safety teams asked to study and solve particular problems.
- Teams that make or do things include people at or near the front lines who are responsible for doing the basic manufacturing, development, operations, marketing, sales, service, and other value-adding activities of a business.
- Teams that run things include managers from the top of the enterprise down through the divisional or functional level.

Numerous team typologies have been identified. One classification of teams includes work teams, parallel teams, project teams, and management teams (2).

- *Work teams:* Continuing work units responsible for producing goods or providing services; memberships are typically stable, well defined, and usually full-time.
- *Parallel teams:* Teams that pull together people from different work units or jobs to perform functions that the regular organization is not well equipped to perform, such as safety teams or quality improvement teams.
- *Project teams:* Teams that produce one-time outputs, such as a new product or service to be marketed by the company, a new information system, or a new plant.
- *Management teams:* Teams that coordinate and provide direction to the subunits under their jurisdiction, laterally integrating interdependent subunits across key business processes.

Another classification scheme includes problem-solving teams, self-managed teams, and cross-functional teams (4).

- *Problem-solving teams:* Members share ideas or offer suggestions on how work processes and methods can be improved. However, these teams are rarely given the authority to unilaterally implement any of their suggested actions.

本书版权归John Wiley & Sons Inc.所有

- *Self-managed work teams:* Groups of employees take on the responsibilities of collectively planning and scheduling work, controlling the pace of work, making operating decisions, and taking action on problems. Fully self-managed work teams even select their own members and evaluate each other's performance.
- *Cross-functional teams:* Teams are made up of employees from about the same hierarchical level but from different work areas, who come together to accomplish a specific task.

Teams can also be classified based on their degree of autonomy (from low to high) in the following five team types (4).

- *Traditional work teams:* Workers perform core production activities but have no management responsibility or control.
- *Quality circles:* Members join voluntarily with no financial rewards. The team has the responsibility for making suggestions but does not have the authority to make and implement decisions. The problem-solving domain is limited to quality- and productivity-related issues and cost reduction.
- *Semiautonomous work teams:* Workers manage and execute major production activities.
- *Self-managing teams (or autonomous work teams):* Members have control over the management and execution of an entire set of tasks—from the acquisition of raw materials through the transformation process to shipping, including all support activities, such as quality control and maintenance, required to produce a definable product. The product could be a definable part of a production process as well as a completed process.
- *Self-designing teams:* These have all the characteristics of self-managing teams. In addition, they have control over the design of their teams and decide such issues as what tasks should be done and who should belong to the teams.
- *Virtual teams:* Virtual teams are a special case and can fall into most of the above categories. These teams work together primarily through electronic media. Teams may meet in person occasionally but work online most of the time due to members not working in the same physical location. The coronavirus disease 2019 (COVID-19) pandemic saw many teams that previously met in person shift to virtual teams. Virtual teams are discussed more thoroughly later in this chapter.

While teams may primarily be implemented as one of the kinds listed above, it does not preclude teams from occasionally acting as another form/style of team. For instance, during the early days of running COVID-19 tests, there was a severe materials shortage that delayed many laboratories' ability to run tests. Teams in Israel quickly turned from semiautonomous work teams focused on getting tests run to problem-solving teams to figure out how to deal with the shortage and ever-increasing need for test results. They developed a viable alternative in pooled testing, where multiple individual samples were analyzed in a single test. If no one in the sample tested positive, then no further analysis was needed, and the laboratory had just saved materials and time. For tests with positive results, each individual sample could be analyzed (5).

Why Define "Team" So Precisely?

By defining the term "team" precisely and paying attention to specific business needs as they relate to team attributes, informed decisions can be made to design and manage teams most effectively. Furthermore, a clearly defined notion of what is in fact a team provides a set of expectations for both management and team members that guides performance management, rewards, team member selection, and resource allocation. The definition should guide the structure, purpose, and composition of the teams, as well as the decision whether to employ them in a particular situation. "But wait," you might be thinking. "Isn't the team the 'thing' in business organizations these days?" Well, it's certainly true that teams are quite popular and that their implementation has produced good results for many businesses (6). However, that does not mean that every organization or every department in an organization should invest heavily in creating teams or, if they do, that they should expect the same results.

Guidelines for Choosing Whether To Have Teams

Now that we have discussed why an organization would want to have teams, we are in a position to discuss how to determine whether the use of teams is appropriate for given situations and circumstances.

Common Purpose

One precondition is for the teams to have a common purpose. "A common, meaningful purpose sets the tone and aspiration . . . inspires both pride and responsibility . . . conveys a rich and varied set of meanings to guide what the team needs to do, particularly in meeting its goals . . . gives teams an identity that reaches beyond the sum of the individuals involved . . . keeps conflict constructive by providing a meaningful standard against which to resolve clashes between the interests of the individual and interests of the team" (7). A common purpose is not a nebulous, tautological admonition exhorting people to "work together," nor is it a far-removed objective such as "corporate profitability."

本书版权归John Wiley & Sons Inc.所有

Common purpose for a team consists of objectives and goals that can be reached only if all members of the team contribute, and the success of a given member's contribution depends upon the success of other members' contributions. One fundamental difference between low- and high-functioning teams is how clearly the team goal is articulated and how committed team members are to reaching that goal.

Interdependent Tasks

By examining the nature of the tasks that must be performed and the relationships among those tasks, we can sometimes reach an understanding of how each member will contribute to the successful accomplishment of the team's purpose. This understanding should help answer another important question: do the individuals who would make up the team really need to collaborate to accomplish team goals? In particular, we are interested in the degree of interdependence among their tasks. Tasks are interdependent if their progression or completion is influenced by, determined by, or subject to the progression or completion of one another. Stated another way, task interdependence can be thought of as the degree to which the completion of a given task requires that other tasks be completed, the degree to which the given task must be completed for another task to be completed, or the degree to which the individual performing the given task must interact with others to complete the task.

Task interdependence can be thought of as having three types or forms: (i) pooled interdependence, (ii) sequential interdependence, and (iii) reciprocal interdependence (Fig. 15.1). Pooled interdependence occurs when two or more individuals function with relative independence but their combined output contributes to the group's or organization's overall goals. An example of pooled interdependence in a laboratory setting would be two technologists independently reading culture plates, one for the aerobic bacterial culture and the other for the anaerobic culture. When the tests are totaled, the total number of completed tests would be an indicator of the laboratory's productivity.

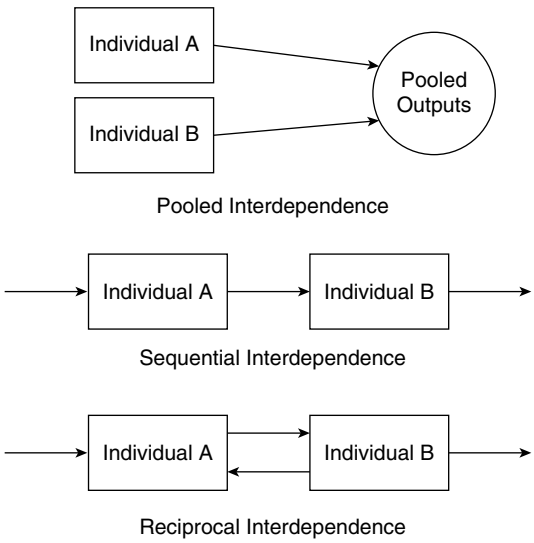


Figure 15.1 Types of task interdependence. (Top) Pooled interdependence; (middle) sequential interdependence; (bottom) reciprocal interdependence.

Sequential interdependence occurs when workers depend upon others for their inputs. The dependency is in only one direction, and if those who provide the inputs do not perform their jobs properly, those who are dependent on them will be significantly affected. The steps have a specific order, and individuals cannot perform their tasks until the tasks that precede theirs are completed. In a laboratory setting an example of sequential interdependence might be specimen accessioning by one individual, specimen processing by a second, and specimen analysis by a third.

Reciprocal interdependence occurs when individuals exchange inputs and outputs. If the performance of any task is compromised, the effect will eventually be visited upon the other tasks. A medical example would be a surgical team wherein the actions of each member influence and are influenced by the actions of the others (7).

It is possible to make rather objective assessments of the type and degree of task interdependence that exists among specific tasks. However, whether the workers who are performing the tasks would agree with the assessment is another matter. Current research indicates that various individuals can perceive the degree of task interdependence of the same set of tasks differently (8). This research also indicates that the level of task interdependence perceived by employees is related to their commitment to their organizations and their work teams. The idea behind this is that as employees perceive their efforts as interdependent with the efforts of others, they become more aware of the contributions they are making to the successful attainment of the organization's goals and to the success of those with whom they are working. According to theory, this heightened awareness should enhance employees' ego involvement with their jobs and cause more positive attitudes toward their organizations and teams (8). The lesson is that it is important for employees to understand how their tasks contribute to (read: "are interdependent with") the success of others' tasks and what the successful performance of these tasks means to the organization.

Costs: a Cautionary Note

In addition to the benefits accrued by the use of teams, considerable costs are associated with their implementation and use. The benefits from the use of teams must

本书版权归John Wiley & Sons Inc.所有

exceed the costs associated with using them. Hours of training are usually required before employees are comfortable with each other and able to function effectively and efficiently as a team. It is also important to train managers and supervisors in the skills required to lead the team. Cross training allows team members to help or "back up" each other. However, cross training is expensive and may be ineffective or impossible if the team members possess different but highly specialized skills, e.g., a surgical team. Further, monitoring and the implementation of feedback systems are needed to inform the team of its progress and help keep everyone on track. This is not to say that teams are not worth it. Rather, it should remind us to be sure that the use of teams is necessary and that the outcomes are desirable before committing resources for their implementation.

We should emphasize that teams are not always necessary. Even if the teams perform well as independent entities and it appears that the teams' goals are congruent with those of the organization, it does not automatically follow that teams are doing the best for the organization. Typically, effective teams require substantial initial investment to design and develop.

Group Process and Teams

Now that we know what is required to create a high-performing team, we can examine basic team attributes and discuss how we can enhance these attributes to create higher-performing teams. Basically, the group process model says that the sum of the individuals' potential plus process gain minus process loss equals group effectiveness (4). Group processes include communication patterns used by team members when they exchange information and ideas, the techniques and processes they use to develop norms and arrive at decisions, the interaction with and the behavior of the leader, the power dynamics within the team, and the way the team resolves conflicts (4). Recognize that the use of teams generates process loss as well as process gain. Process loss includes such things as the time used for team meetings, the extra time it takes for a group to come to a decision, administrative functions that must be performed when people work in teams, and production loss associated with social loafing. (Social loafing is a phenomenon that occurs when some slack off and let others "carry" them by performing the tasks they themselves should be doing.) Process gains are referred to as synergy. For example, when performing a task that requires diverse skills, such as those found in a laboratory, the quality of the decisions and therefore of the output tends to be better than if the individuals worked alone or independently (4).

The group process model is based on the concept that for teams to be worthwhile, process gain must exceed process loss over the long term. The phrase "over the long term" can be illustrated by the following. A number of team-based organizations with which the authors are familiar have weekly team meetings that last approximately 1 hour. These weekly meetings take time away from the teams' performing their production responsibilities and thus represent process loss. Therefore, the meeting time spent planning work and figuring out ways to be more productive must result in the teams' being more productive by working 39 hours and meeting 1 hour than by working 40 hours with no meeting. Stated another way, the process loss resulting from having the meetings is more than offset by the process gain resulting from the implementation of the decisions made at the team meetings, thus demonstrating how teams can enhance productivity.

Awareness of the time spent on team meetings provokes the following questions: "Are all of these meetings necessary, and are they productive?" and "What would happen if a weekly meeting was skipped?" The answer to the last question is that if a meeting is skipped one week, production would probably increase by about 2.5% (the percentage increase from 39 to 40 hours) during that week. By the same token, if meetings were continually missed and if the meetings were productive to begin with, then their omission would lead to problems not getting resolved, fewer suggestions being made, and no suggestions receiving the benefit of refinement by the group. Furthermore, conflicts would smolder and metastasize. Hence, these meetings are looked upon not only as a corrective mechanism for past issues but also as an investment of time for future efficiency and increased effectiveness. That is, while the time used for meetings represents one component of process loss, the results of the meetings will be process gain.

It should also be noted and understood that team meetings do not automatically ensure net process gains. There are numerous guides and techniques for conducting effective meetings (see also chapter 9 of this volume), and the details are not repeated here. However, some general guidelines are in order.

- Have a clear purpose or objective for the meeting. Can the objective be accomplished more efficiently in another format, perhaps by posting information on a web page or in a newsletter?
- Have an agenda and distribute it in advance of the meeting. Be sure that each item on the agenda addresses the goals of the meeting.
- Make sure the right people are at the meeting.

本书版权归John Wiley & Sons Inc.所有

- Be sure that all team members understand the format of the meetings. Ample opportunity for input from each member should be provided. Input from those who are more reserved, thoughtful, or introverted should be solicited.
- When action is required, tasks should be assigned, resources allocated, and action items followed up. If this is not done, the message imparted is that the team is not a serious entity and the products and outcomes of the meetings are not important.

Selecting Team Members

Skill requirements for team members can be categorized into three types: (i) technical or functional expertise, (ii) problem-solving and decision-making skills, and (iii) interpersonal skills. While members can possess these skills when the team is formed or develop them after it is in place, team performance will erode without them. Thus, it is important that team members be selected based on either possessing these skills or having a strong aptitude for their development. These three basic skill categories are used to set the criteria for team member selection. In practice, these categories take various forms and degrees, depending on the type of team. For example, one can expect task-related skills for a management team to be drastically different from those for a work team. Also, decision-making skills and interpersonal skills in those two contexts are likely to differ to a large extent (7).

While the technical expertise and decision-making skills may differ across teams depending upon their goals, objectives, and methods, the required team-related skills tend to be common among all types of teams. Team-related skills can be further categorized as shown in Table 15.1. New team members can be internally or externally recruited, and the tools that the organization uses to select new team members may differ depending on whether the candidates already work for the organization or come from outside. Internal candidates are those that already work for the organization, and managers have knowledge about their knowledge, skills, and abilities (KSAs), as well as their personality and past performance. Thus, the need for internal candidates to complete a variety of selection tests to gain information may be low compared to that for external candidates. Sample questions from a selection instrument designed to measure these attributes are shown in Table 15.2.

In addition to written tests, other selection tools can be developed to measure KSAs. For example, structured interviews can be designed to measure whether candidates have adequate levels of these KSAs. Interviews can also

Table 15.1 Knowledge, skill, and ability (KSA) requirements for teamwork[a]

Category	Type and requirements
Interpersonal KSAs	Conflict resolution KSAs Recognize and encourage desirable, but discourage undesirable, team conflict Recognize the type and source of conflict confronting the team and implement an appropriate conflict resolution strategy Employ an integrative (win-win) negotiation strategy rather than the traditional distributive (win-lose) strategy
	Collaborative problem-solving KSAs Identify situations requiring participative group problem solving and utilize the proper degree and type of participation Recognize the obstacles to collaborative group problem solving and implement appropriate corrective actions
	Communication KSAs Understand communication networks and utilize decentralized networks to enhance communication where possible Communicate openly and supportively, that is, send messages that are (i) behavior- or event-oriented, (ii) congruent, (iii) validating, (iv) conjunctive, and (v) owned Listen without judging and appropriately use active listening techniques Maximize consonance between nonverbal and verbal messages and recognize and interpret the nonverbal messages of others Engage in ritual greetings and small talk, recognizing their importance
Self-management KSAs	Goal-setting and performance management KSAs Help establish specific, challenging, and accepted team goals Monitor, evaluate, and provide feedback on both overall team performance and individual team member performance
	Planning and task coordination KSAs Coordinate and synchronize activities, information, and task interdependencies among team members Help establish task and role expectations of individual team members and ensure proper balancing of workload in the team

[a] Adapted from reference 9.

本书版权归John Wiley & Sons Inc.所有

Table 15.2 Example items from the teamwork-KSA test[a]

1. Suppose that you find yourself in an argument with several coworkers about who should do a disagreeable but routine task. Which of the following would likely be the most effective way to resolve this situation?
   a. Have your supervisor decide because this would avoid any personal bias.
   b. Arrange for a rotating schedule so everyone shares the chore.*
   c. Let the workers who show up earliest choose on a first-come, first-served basis.
   d. Randomly assign a person to do the task and don't change it.
2. Your team wants to improve the quality and flow of the conversations among its members. Your team should:
   a. Use comments that build upon and connect to what others have said.*
   b. Set up a specific order for everyone to speak and then follow it.
   c. Let team members with more to say determine the direction and topic of conversation.
   d. Do all of the above.
3. Suppose you are presented with the following types of goals. You are asked to pick one for your team to work on. Which would you choose?
   a. An easy goal. This will ensure that the team reaches it, thus creating a feeling of success.
   b. A goal of average difficulty. The team will be somewhat challenged, but they will be successful without too much effort.
   c. A difficult and challenging goal that will stretch the team to perform at a high level. The goal is attainable so that effort will not be seen as futile.*
   d. A very difficult or even impossible goal. Even if the team falls short, it will at least have a very high target to aim for.

[a] Adapted from reference 9. Asterisks indicate correct answers.

help find individuals who want to work in teams. Assessment center techniques can be used to measure candidates' leadership and other social skills through group exercises. Biographical data measurement may provide information about candidates' KSAs in dealing with social problems, especially those focusing on experiences candidates had in previous jobs, school, and recreational activities involving teams. One can also integrate team-related KSAs into the recruiting process by communicating the importance of these KSAs through such methods as realistic job previews (9).

It is important that current team members participate in the selection of new members. Allowing the team to provide input for selecting new members can increase members' commitment to the team. Also, it should encourage members to help new hires be successful. However, it can also lead to decreased team diversity if team members are more comfortable hiring people more like themselves.

The following is an example of how individual traits may affect various attributes of teams, including productivity. In a study of work teams conducted at an apparel factory, certain dispositions of team members were found to be negatively related to team performance or quality. For example, team members who possessed a higher degree of aggression and autonomy were less likely to report high levels of team commitment and team cohesion, two factors often regarded as important antecedents of team performance. In addition, teams were found to have more difficulty in controlling quality when members were talkative or valued extraneous communications among team members at the expense of attention to the team's tasks. Teams with more members willing to use cross-training skills tended to have higher productivity, quality, cohesion, and commitment (10).

In teams, as elsewhere, success breeds success. There is evidence that team members' preferences for teamwork are related to the effectiveness of the team. Hence, it is important for teams to experience success early. This starts with member selection.

Task- and Process-Related Training

Task-related training focuses on the actual tasks for which the team is responsible. Because of rapidly changing technology, the associated technical skills and knowledge require continuous upgrading. Hence, task-related training is an ongoing process. Training programs should be designed to satisfy the team's need for particular technical skills. Consequently, the design should consider each individual member's current abilities, interests, and professional direction. Task-related training can be conducted through formal classroom instruction, on-the-job training, and member-to-member mentoring (11). A variety of e-learning methods are also available, which include webinars, online content, and simulations that allow participants to practice necessary skills.

Research indicates that when team members possess the appropriate team- or process-related skills (Table 15.1), there will be positive effects on team performance (9). One of the most important of these skills is the ability to communicate well. Teamwork relies on collective actions and decisions. Furthermore, team members accomplish these actions and make these decisions through the exchange of opinions, negotiation, persuasion, compromise, and collaboration. Thus, communication skills and group decision-making skills are essential for collective creation and for relationship management. Training to enhance these skills can start before the work teams are formed and should be made available on an ongoing basis as teams develop and mature.

Numerous authors and consultants have also endorsed team awareness training. The purpose of team awareness training is to give employees an overview of what teams

本书版权归John Wiley & Sons Inc.所有

are all about, why the organization is adopting them, and how employees can benefit personally from their team membership (11). Self-managing work teams, and to a lesser degree other types of teams, may take over leadership roles and responsibilities such as scheduling work, safety training, selecting new team members, assigning team members to tasks, and obtaining necessary resources to perform their work. Thus, training on how to do these managerial tasks is required for teams to be successful.

Leading Teams

General Ideas about Leadership: a Brief Review

Leadership is a process in which one individual exerts influence to structure the behavior of other people within a group (12). Various leadership theories have hypothesized about leadership roles and behaviors, their relationship with group performance, and external conditions that moderate such relationships. Two of the earliest behavioral leadership theories came from studies performed at The Ohio State University and the University of Michigan. The Ohio State study categorized various leadership behaviors into two basic types, labeled "consideration" and "initiating structure." The Michigan study also identified two basic categories of leadership behaviors, labeled "relationship-oriented behaviors" and "task-oriented behaviors." The consideration and relationship-oriented behaviors focus on relationship building and maintenance between leaders and followers. These behaviors have also been referred to as "supportive behaviors" and include acting friendly toward followers, respecting followers' ideas and feelings, appreciating their contributions, recognizing their accomplishments, and showing concern for their welfare and needs (12).

Both initiating structure and task-oriented behaviors focus on task completion. These include planning, organizing, and scheduling work, assigning tasks, coordinating activities, and providing the necessary direction, materials, and support. Initiating structure and task-oriented behaviors have also been termed "directive behaviors" (12). There are numerous other typologies of leadership behaviors, but most tend to be subcategories of the two main categories described above. Therefore, we use the Ohio State designations for this discussion.

Leaders need to engage in both consideration and initiating structure behaviors, as employees under the right circumstances appreciate each. For example, when the employee is new or inexperienced or lacks knowledge, guidance and direction are needed and usually appreciated. This calls for the leader to provide needed guidance and direction, that is, initiate structure. Employing consideration at such a time would not address the employee's problem and likely be seen as not helpful.

Even though these examples may be clear, in the workplace we are often confronted with ambiguous and conflicting situations. For example, what about the situation in which the task is simple (suggesting that initiating structure is not needed) but the employee is inexperienced (suggesting that initiating structure is needed)? In such a case, managerial judgment is required. One alternative might be to ask the employee what he or she needs. Those with an internal locus of control may ask for time to figure it out, while those with a more external locus of control may ask for instructions. Managers or team leaders must then balance the constraints of the situation. Suppose that time is of the essence and you do not have time for them to figure it out, yet figuring things out is a skill employees must have to successfully work on this team. A leader must make the tough decisions in situations in which there are no obvious answers. It is also important to note that initiating structure and consideration are not mutually exclusive. Managers can engage in both types of behavior as they are required. It is up to managers to apply judgment along with the theories and concepts to the situations they face.

Leadership in a Team Environment

Performing successfully as a team leader requires a number of skills (13). Successful team leaders know that team performance comes from collective effort and action. An important focus is to motivate team members to support collective performance. To do this, team leaders need to accomplish several objectives. First, "clarify purpose and goals, build commitment and self-confidence, strengthen the team's collective skills and approach, remove externally imposed obstacles, and create opportunities for others" (13). Second, keeping in mind that team success depends on the combined contributions of all members of the team, team leaders should, as much as possible, involve team members in decisions that affect the team and its performance. This approach helps keep members "in the game" and gives them an additional stake in team outcomes. To this end, team leaders should consciously avoid any action that might threaten the desire of team members to make contributions. For example, team leaders should avoid ridiculing or harshly criticizing members' ideas and opinions. Third, it is the team leader's role to develop and facilitate team members, not control them. Consonant with this objective, leaders must decide how much autonomy to give to members, when to make decisions alone or with the team, and how much responsibility to give inexperienced members: too much, and they may fail and hurt the team's performance and their own development; too little, and they may never develop, develop too slowly, or become discouraged.

Team leaders can take on other roles. For example, they can be (i) liaisons between the team and other parts of the

本书版权归John Wiley & Sons Inc.所有

organization or even other organizations; (ii) resource providers, assisting the team in defining their resource needs and helping to secure those resources; (iii) counselors, helping team members develop problem-solving skills; (iv) mentors, guiding team members to develop organizational savvy; (v) teachers, passing on technical information to team members; or (vi) devil's advocates, challenging the team process of decision making, interpersonal relationships, and progress toward the team's goal (14). Team leaders may also be working members of the team, performing team-related tasks within the purview of the team. One of the most difficult tasks that a team leader has is to fire an employee. Removing a member from a team is exceedingly difficult for team members, yet a member of the team who is disruptive and cannot perform their share of the work can lead to frustration and team dysfunction.

Team leaders and members should be aware that the leader's role may change with the maturity or competency of the team (15). Team leaders can guide members to perform some of the key functions of leadership, which is associated with what has been termed "self-managing teams." Research and experience have shown that self-managing teams can be highly effective and provide a net savings by reducing the number of managerial employees required.

Team Leader Selection

There are a number of ways to select a team leader. The leader can be assigned externally, be elected internally, or emerge naturally, or leadership may be rotated among team members. Different methods of leader selection have different effects on the leader's legitimacy—how followers perceive the leader's source of authority and respond to the leader. Electing the team leader makes it more likely that the followers will identify with the leader, have more sense of responsibility to the leader, and perceive a greater investment in him or her. However, elected leaders will be more likely to face criticism from followers for performance failure. Research has shown that teams whose leaders were elected by team members performed better than teams with no leader or teams whose leaders were appointed (16) and that, compared to appointed leaders, elected leaders received higher ratings from the members on responsiveness to members' needs, interest in the group task, and competence (17).

A naturally emergent leader can be expected to receive responses from team members similar to responses to an elected leader. In both selection processes, team members evaluate the potential leader to determine if the individual possesses the appropriate qualities of a team leader. The difference in the processes is the timing of the evaluation, because with elected leaders, potential leader candidates are evaluated before work begins on the group assignments rather than over the course of the project, as happens with naturally emergent leaders. However, when leaders emerge on their own, they may shift the team's direction depending on the immediate task and goal. This may not be conducive to the smooth and timely achievement of the organization's and team's goals. There are other dangers associated with waiting for a team leader to emerge. First, unless the team's production norms are clear and high, an emergent leader may lead the team away from the purpose for which the team was formed. Second, two or more rival leaders may begin to emerge, and coalitions may form around them and split the team. Finally, a leader may not emerge or may take too long to do so.

Rotating leaders is another way to generate and maintain team-leading function. Here, the focus is on the function of the leader position rather than who the team leader is. Rotating leaders tends to work when the task is clearly defined and the direction, vision, and purpose of the team are well understood and do not depend upon who the leader is. This is also an excellent way to give leadership experience to the team members and encourage each member to buy in to the team's purpose.

Another approach for team leader selection is through a process in which both upper management and the team members participate. Participative selection, if properly structured and guided, can have at least four positive results.

- Selecting high-quality leaders
- Engendering high levels of participant satisfaction
- Fostering better understanding of the leader's job
- Creating positive expectations that enhance the chances of the leader's success through the process of self-fulfilling prophecy (4)

Goal Setting, Performance, and Rewards

Goal Setting and Performance

One of the most viable and successful motivational techniques to appear in the management literature is goal setting. Goal-setting theories suggest that goals can improve performance because they generate, direct, and sustain effort (18). For goals to have the most positive effect, they should be specific, rather than general or vague; difficult but attainable, rather than easy; and accepted by the team. Attempts to reach them should be accompanied by feedback (18).

General or vague goals, such as "do your best," do not result in the higher levels of performance that occur when goals are specific, e.g., "increase production by 10%." The specificity of the goal acts as a guide and stimulus, allowing employees to make reasonable inferences about the effort and resources that will be required to obtain the goal.

本书版权归John Wiley & Sons Inc.所有

Simply setting difficult goals is not automatically effective. Workers must see the goal as attainable. If the goal is unreasonably high and perceived as unattainable, it may discourage effort rather than motivate it. At the same time, a goal must be accepted by those who will strive to attain it. If a goal is not accepted, individuals are unlikely to strive very hard to reach it.

The final dimension in goal-setting theory is feedback. When people have accepted a goal and are striving to achieve it, they need to know how they are doing. This knowledge helps them identify discrepancies between where they are and where they want to be and between what they are doing and what they should be doing.

Goal Setting and Teams

The performance-enhancing effect of goal setting has been found not only at the individual level but also at the group level (18). The results of research with groups parallel those obtained with individuals in terms of goal specificity, difficulty, attainability, acceptance, and feedback (9). Conversely, team effectiveness can be lowered because of a lack of unity or clarity about goals (9). Furthermore, improper assessment of goal difficulty leads to team failure (19).

As with individuals, team goals can be assigned or participatively set. Which technique to use depends on the type of team and the tasks the team is assigned. Studies show that participatively setting goals is likely to enhance the acceptance of goals by team members, increase congruence between individual and team goals, lead to better-quality goals and satisfaction with the process (20), and increase the likelihood of producing positive outcomes. Another possible benefit of team members participating in goal setting is the cohesiveness that can be generated by such interaction. Further, as teams discuss various goal levels, individual members become aware of their teammates' strengths, weaknesses, and overall capabilities. This awareness should assist members in making sound and realistic judgments concerning the team's capabilities as a unit.

Evaluating Teams and Team Members

Performance evaluation gives feedback to the team and should be used to guide the team in making any adjustment that may be needed. Teams need to be evaluated as units. A team's achievement can be evaluated based on (i) the degree to which the results that a team delivers are acceptable to those who receive them, (ii) the team's being able to work effectively together in the future, and (iii) individual members' being more satisfied than frustrated in achieving their personal goals (21).

When the collective outcome (team performance) is assessed, individual team members' contributions must be evaluated as well (22). Different individuals may make disproportionate contributions, which can cause resentment among team members if not addressed. At the same time, the nature of a given team may be that one individual (or a subset of individuals) is simply more capable than the others. In such cases, others may respond by relieving that individual of some of the administrative or "housekeeping" duties and supporting him or her in other ways. Team and management recognition of the additional contribution or even providing some additional incentives for this larger contribution may be appropriate, but caution must be used to avoid conflict or social loafing among team members. Even so, it is important to monitor individual performance to understand the impact of variations in team member performance, particularly if a member of the team is not contributing their fair share to team outcomes (23). Most of the time, a team's visible outcome is the result of a collective effort. Consequently, evaluation of individual team members can be problematic. Some experts suggest creating a behavioral instrument based on the sample KSAs for teamwork displayed in Table 15.2. Honest and constructive peer evaluation is also important.

Rewarding Team Members

There are a variety of ways to reward teams that can have a long-term impact on their motivation. One philosophy is to reward all team members the same, emphasizing that this is a team effort and team members get the same level of pay and the same bonus. However, as we know from sports, some individuals can make a much greater contribution to team performance than other individuals based on the position they hold or their innate abilities to perform at higher levels than other team members. As such, should they be paid more for their ability or contribution? Is it fair to pay an individual that makes a larger contribution the same as other members? Should team members be paid the same, or should pay be differentiated within the team?

There are two types of equity that must be considered: (i) whether the team is fairly rewarded compared to other teams and (ii) whether team members are fairly paid based on their relative contribution compared with other members of their own team.

Some managers may suggest giving rewards to individuals who exhibit outstanding performance on a team. In general, we discourage such action. In fact, there are times when doing so can be counterproductive. For example, when teams are new and have been recently introduced in an organization, there may be a tendency by individuals to resist sacrificing their autonomy for the sake of the team. To offer individual rewards during this time would, in our view, undermine the team concept and the idea of subordinating individual goals to team goals. For teams to prosper, especially during the initial stages of their formation, we suggest that all rewards be at the team level and all

本书版权归John Wiley & Sons Inc.所有

recognitions be for team results. Later, individual rewards may be appropriate, but this action should be carefully considered and done with extreme caution. Individuals that work on more than one team or are only part-time team members represent other complex compensation situations. We recommend discussing the compensation options with your firm's human resource department.

Virtual Teams and Remote Work

Virtual teams are teams whose members are usually geographically dispersed but are linked together and communicate by using information and communications technology (ICT) to work toward a common goal (for example, see references 24 and 25). Virtual teams have become one of the most relevant and applicable types of work arrangements designed to meet rapidly changing demands of diversified and globalized markets (24). Since virtual teams do not require team members to be in the same physical location, the pool of potential applicants is significantly expanded. Thus, organizations have greater chances of attracting the most talented individuals for specific tasks. This, in turn, results in greater competitive advantages in global markets.

Fast-developing technologies have made virtual teamwork more feasible (24) by providing virtual teams with tools for the members to communicate with each other either asynchronously or synchronously. Modern project management software allows for close coordination and provides a common source for monitoring project progress and for making sure that changes to the project are known by all team members.

The use of virtual teams has also become a technique for organizations to effectively save resources by reducing business trips, saving commute time, and lowering costs such as real estate expenses (for example, see reference 26). Compared with other types of teams, virtual teams can perform many of the same functions as traditional teams. However, the quality of the rapport and the degree of cohesion among the virtual team members may not be as high as that of face-to-face teams (25). Consequently, virtual teams are more likely to be task oriented unless there are in-person acquaintances between the team members (25). Since virtual team members typically do not interact with each other in the same way as face-to-face team members, the way in which virtual teams are managed is likely to differ as well (4). That is, a traditional hierarchy may not work well to manage virtual teams, particularly when the degree of team virtualness is high (27). Instead, research shows that shared team leadership may be more effective to improve virtual team performance no matter how much team virtualness there is (27).

Prior to implementing virtual teams, an organization should consider whether a virtual team is the optimal type of team to achieve the desired goal (4). Because the ways in which virtual teams work differ from those of face-to-face teams, the virtual team composition needs to fit with virtual teamwork, and as mentioned above, managerial approaches are likely to differ in order to effectively lead virtual teams.

On the other hand, since ICT has been enhanced and come into widespread use, many organizations have access to popular software tools at relatively low costs. This means that most of today's teams have some degree of virtualness (28). Consequently, it is hard to find a team that never relies on virtual interactions but communicates totally face-to-face (26, 28). In this respect, it may no longer be meaningful to define pure virtual teams versus pure face-to-face teams. Thus, recent trends of virtual team definitions regard virtualness as a team characteristic and focus more on the extent or degree of team virtualness (26, 29). The extent or degree of team virtualness is likely to rest on "the nature of the tasks, technological resources, and members' skills and capabilities" (26).

The COVID-19 pandemic has unexpectedly pushed most organizations into accepting at least some degree of virtual teamwork. This has effectively rendered virtual teams a standard feature regardless of the type of organization in question. That is, the degree of virtualness has dramatically increased across teams all over the world, and virtual teamwork has become the new norm during the pandemic. In the meantime, the members of such teams were forced to learn technological skills to communicate with each other virtually and to adapt to the changes in a short period of time (29). Klonek and his colleagues (29) investigated how the COVID-19 pandemic impacted the way in which team members interact in response to such a drastic change. They found that virtual team members in the COVID-19 posttransition phase (June to August 2020) showed a higher quality of coordination and conflict management than those in the early transition phase (March to May 2020). That is, team members who had to communicate in virtual settings were able to adapt to the new environment and enhance the quality of virtual collaboration. As the pandemic persisted, they became more accustomed to communicating virtually.

However, the use of virtual teams can create challenges for organizations and the individuals serving on those teams. Virtual teams can make employees feel increasingly isolated, increase chances of misunderstanding among team members, and create conflicts that can be hard to resolve. Members of virtual teams are also likely to have individual responsibilities in addition to their team assignments or be members of more than one team. The COVID-19 pandemic highlighted additional challenges team members may have when working at home, including insufficient computer or internet access and family/household demands. In order to ensure that team

本书版权归John Wiley & Sons Inc.所有

members are successful, it is vital that organizations help provide the resources needed for employees to work. Furthermore, virtual exchanges may be less productive because members may attempt to multitask during meetings when they cannot be observed. Having extended meetings or having several online team meetings a day can be overwhelming and cause "Zoom fatigue." To minimize the potential problems of virtual teams and take advantage of their positive attributes, we suggest that managers:

- Use multiple forms of electronic communications (e.g., emails, text messages, video conferencing, and/or conference calls) to liven up exchanges and encourage individuals to communicate information in different ways depending on the information to be shared, the work to be done, or the decisions to be made.
- Make sure that team members have access to all forms of electronic devices and the necessary secure data access that they will need and that they are comfortable using them.
- Keep in mind that members of the team may be in different time zones or working under different schedules when virtual meetings are scheduled.
- Balance the needs of team members both with regard to making the connection that comes from seeing each other on web meetings and their level of Zoom fatigue. Occasionally allowing team members a break from being on camera or having to look at others on a screen can provide some relief.
- As recommended above, limit the meetings to when necessary and have an agenda.

Global Teams (a Special Case of Virtual Teams)

Global teams based on geographical distance were often operating as virtual teams well before the pandemic. As such, much of the material in the section above applies to global teams. However, global teams pose additional challenges, including operating in different time zones and having fundamentally different pay packages and vacation/holiday schedules. Globalization has transformed how business is conducted. A survey of global managers indicated that most of their time was spent working with global teams, and two-thirds of the sample said that they were on multiple global teams. Companies "go global" for a number of reasons, including to (i) reach new markets, (ii) realize labor savings, (iii) access cheaper raw materials, (iv) obtain and leverage scarce talent, and (v) realize supply chain advantages. Hence, global companies should not be thought of as a set of stand-alone organizations across the globe but as integrated operations designed to obtain the value of being effective and efficient global entities.

Global teams deal with issues that transcend countries and the cultures in which any single operation is embedded. Members of global teams may have to communicate using languages in which they are not fluent and interact with people from different cultures who have different mental models of how to approach problems, make decisions, interact with others, and handle conflict (30). Another issue arises from cultural norms surrounding time away from work. U.S. team members will have challenges working with colleagues in Europe during July and August, when employees take four-week vacations, and with colleagues in China in May, due to the Golden Holiday period. Further issues with global teams include managing tensions from team members receiving different pay packages based on their location. Again, this is a situation which calls for working with Human Resources.

Given the nature and challenges faced by global teams, more time and resources must be invested for them to be effective. Consideration must be given to the characteristics of the individuals who are placed on global teams. Successful global team members must have language, technical, and social skills as well as an understanding of how to work with those who operate in different cultures. If possible, meeting in person greatly helps initial team formation; however, in light of the COVID-19 pandemic, online meetings may be used. Also, local issues and obligations often trump global responsibilities. Clear goals, work structure, and performance criteria must be established and communicated. Again, note that responsibility for meeting performance goals may be defined differently by people from other cultures. For example, in some cultures, a deadline is absolute, and in other cultures, it is fluid. These differences must be discussed up front, since they tend to upset people and damage relationships between teammates when encountered while working on a task. Finally, one must allow for misunderstandings and complications. Training on managing team conflict may be especially helpful for global team members.

Common elements of effective teams are trust and commitment among members. One must recognize that distance and culture can be significant barriers for building these elements, and thus, members of international teams need to put forth extra effort to ensure a successful and effective team. Furthermore, one can even argue that teams within a diverse country like the United States offer challenges similar to those encountered when people from different cultures work together.

SUMMARY

Research and experience have repeatedly demonstrated that teams enhance productivity, individual performance, team member job satisfaction, and commitment to the organization. However, the use of teams is not easy, and it

本书版权归John Wiley & Sons Inc.所有

is certainly not free. In fact, using teams can have important and salient drawbacks. Such drawbacks must be looked upon as investments in the business before teams are implemented. Organizations should be as sure as they can be that their investment in teams will bring forth worthwhile returns. That is, the use of teams should be evaluated just like any other investment.

KEY POINTS

- The effectiveness of a team can be determined by:
  - The acceptability of its results.
  - The ability of its members to work together in the future.
  - The value of the team experience to each member.
- Conditions that facilitate effective teamwork are:
  - A group structure that promotes competent work on the task.
  - Support and reinforcement of excellence by the organization.
  - The availability of expert coaching and process assistance.
- The essence of a team is a common commitment leading to specific performance goals.

GLOSSARY

Common purpose A state that is achieved when team members fully understand the team's purpose or reason for existing and there is significant goal congruence.

Gainsharing A financial plan in which improved group productivity determines the amount of money that is shared among the company, investors, and members of the group.

Goal congruence The degree to which team (or group) members' individual goals coincide with the team's (or group's) goals.

Goal setting The process by which team and/or individual goals are determined, communicated, and agreed upon.

Group effectiveness The sum of the group members' individual capabilities, plus process gain, minus process loss.

Group process The way groups get things done, including communication patterns, decision-making methods and techniques, leader behavior and interaction, power dynamics, conflict resolution methods and techniques, and the way members interact with each other.

Leadership legitimacy The degree to which a team or group leader is accepted by both the team or group members and the employing organization.

Participative selection A process in which team members choose new members of their team based on team-related criteria that were determined and agreed upon prior to candidate identification.

Process loss (gain) The degree to which group processes inhibit (enhance) the successful completion of group objectives.

Task interdependence The degree to which a task's progression or completion is influenced by, determined by, or subject to the progression or completion of one or more other tasks.

Work group Two or more individuals who interact primarily to share information and to make decisions that help each other perform within their areas of responsibility.

Work team Two or more individuals whose individual efforts result in a performance that is greater than the sum of those individual parts and who have different tasks but work together adaptively to achieve specified and shared goals.

Zoom fatigue The exhaustion one feels after any kind of video call or conference.

REFERENCES

1. **Batt R.** 2004. Who benefits from teams? Comparing workers, supervisors, and managers. *Ind Relat* **43**:183–212.

2. **Cohen SG, Bailey DE.** 1997. What makes teams work: group effectiveness research from the shop floor to the executive suite. *J Manage* **23**:239–290.

3. **Yang SB, Guy ME.** 2011. The effectiveness of self-managed work teams in government organizations. *J Bus Psychol* **26**:531–541.

4. **Robbins SP, Judge TA.** 2019. *Organizational Behavior*, 18th ed. Pearson, New York, NY.

5. **Hattori K.** 2020. Pooling method allows dozens of COVID-19 tests to run simultaneously. Medical Xpress. https://medicalxpress.com/news/2020-03-pooling-method-dozens-covid-simultaneously.html. Accessed 19 December 2022.

6. **Bishop JW, Scott KD, Burroughs SM.** 2000. Support, commitment, and employee outcomes in a team environment. *J Manage* **26**:1113–1132.

7. **Katzenbach JR, Smith DK.** 1993. *The Wisdom of Teams: Creating the High-Performance Organization*. Harvard Business School Press, Boston, MA.

8. **Bishop JW, Scott KD.** 2000. An examination of organizational and team commitment in a self-directed team environment. *J Appl Psychol* **85**:439–450.

9. **Stevens MJ, Campion MA.** 1994. The knowledge, skill, and ability requirements for teamwork: implications for human resource management. *J Manage* **20**:503–530.

10. **Scott KD, Townsend A.** 1994. Teams: why some succeed and others fail. *HR Mag* **38**:62–67.

11. **Orsburn JD, Moran L, Musselwhite E, Zenger JH.** 1990. *Self-Directed Work Teams*. Business One Irwin, Homewood, IL.

12. **Howell JP, Costeley DL.** 2001. *Understanding Behaviors for Effective Leadership*. Prentice Hall, Upper Saddle River, NJ.

13. **Katzenbach JR, Smith DK.** 1993. The discipline of teams. *Harv Bus Rev* **71**:111–120.

14. **Aranda EK, Aranda L, Conlon K.** 1998. *Teams: Structure, Process, Culture, and Politics*. Prentice Hall, Upper Saddle River, NJ.

本书版权归John Wiley & Sons Inc.所有

15. Carew DK, Parisi-Carew E, Blanchard KH. 1986. Group development and situational leadership: a model for managing groups. *Training Dev J* **40**:46–50.

16. Goldman M, Fraas LA. 1965. The effects of leader selection on group performance. *Sociometry* **28**:82–88.

17. Ben-Yoav O, Hollander EP, Carnevale PJD. 1983. Leader legitimacy, leader-follower interaction, and followers' ratings of the leader. *J Soc Psychol* **121**:111–115.

18. Locke EA, Latham GP. 1990. *A Theory of Goal Setting and Task Performance*. Prentice Hall, Englewood Cliffs, NJ.

19. Kukla A. 1975. Preferences among impossibly difficult and trivially easy tasks: a revision of Atkinson's theory of choice. *J Pers Soc Psychol* **32**:338–345.

20. Levine JM, Moreland RL. 1990. Progress in small group research. *Annu Rev Psychol* **41**:585–634.

21. Hackman JR. 1990. *Groups that Work (and Those that Don't): Creating Conditions for Effective Teamwork*. Jossey-Bass Publishers, San Francisco, CA.

22. Tesluk P, Mathieu JE, Zaccaro SJ. 1997. Task and aggregation issues in the analysis and assessment of team performance, p 197–224. *In* Brannick MT, Salas E, Prince C (ed), *Team Performance Assessment and Measurement*. Lawrence Erlbaum Associates, Publishers, Mahwah, NJ.

23. Harkins SG. 1987. Social loafing and social facilitation. *J Exp Soc Psychol* **23**:1–18.

24. Gressgård L. 2011. Virtual team collaboration and innovation in organizations. *Team Perform Manage* **17**:102–119.

25. Robbins SP, Coulter MK, DeCenzo DA. 2020. *Fundamentals of Management*, 11th ed. Pearson, New York, NY.

26. Martins LL, Gilson LL, Maynard MT. 2004. Virtual teams: what do we know and where do we go from here? *J Manage Stud* **30**:805–835.

27. Hoch JE, Kozlowski SW. 2014. Leading virtual teams: hierarchical leadership, structural supports, and shared team leadership. *J Appl Psychol* **99**:390–403.

28. Griffith TL, Neale MA. 2001. Information processing in traditional, hybrid, and virtual teams: from nascent knowledge to transactive memory. *Res Organ Behav* **23**:379–421.

29. Klonek FE, Kanse L, Wee S, Runneboom C, Parker SK. 2021. Did the COVID-19 lock-down make us better at working in virtual teams? *Small Group Res* **53**:1–22.

30. Stahl GK, Maznevski ML, Voigt A, Jonsen K. 2010. Unraveling the effects of cultural diversity in teams: a meta-analysis of research on multicultural work groups. *J Int Bus Stud* **41**:690–709.

APPENDIX 15.1 Representative Websites

National Association for Healthcare Quality

http://www.nahq.org (accessed 17 December 2022)

Publications related to quality healthcare, including team building

BusinessTrainingMedia.com, Inc.

http://www.business-marketing.com (accessed 17 December 2022)

Videos and training packages, including team building

Clinical Laboratory Management Association (CLMA) > Online Education Center

https://www.clma.org/onlineeducationcenter (accessed 17 December 2022)

Links to CLMA's library of on-demand courses, including effective team building

本书版权归John Wiley & Sons Inc.所有

16

Labor Relations

Emily A. Snavely and Lynne S. Garcia

Introduction

Labor Law

National Labor Relations Act (Wagner Act), 1935 • Fair Labor Standards Act (Black Act), 1938 • Labor-Management Relations Act (Taft-Hartley Act) • Labor-Management Reporting and Disclosure Act (Landrum-Griffin Act) • 1974 Amendments to the NLRA • Labor Law Updates

National Labor Relations Board (NLRB)

Description • Function • Structure • Processing of Cases • Authority To Secure Injunctive Relief from a Court • Issues Related to the NLRB

Union Structure

Formal Structure • Union Membership • Function of the Union Steward

Unionization Process

Individual, Group, and Union Image: Reasons Why Employees Join a Union • Relevance for Healthcare Workers

Organizing Campaign

Authorization Cards • The Bargaining Unit • Information Distribution and Solicitation • Election • Certification

Collective Bargaining

Issues for Bargaining • Preparation Phase • Negotiation Phase • Administration of the Agreement • Management Rights Clause • Labor Actions and Disputes

SUMMARY

KEY POINTS

GLOSSARY

REFERENCES

APPENDIXES

Why is it that those who are the quickest to judge are often those in possession of the fewest facts?

JOHN WOODEN

THE TERM "LABOR RELATIONS" HAS BEEN DEFINED as the interactions between an employer represented by management and supervisors and groups of employees who are in bargaining units represented by a union. Labor relations involve the rights of employees, unions, and employers under the law and the interpretation and application of collective bargaining agreements which address issues such as wages, hours, and working conditions. Procedures for resolving contract disputes are also included (1).

Regardless of whether you support or dislike the concept of unionization, it is mandatory that all parties obtain a basic understanding of labor relations, including the law, organizing campaigns, collective bargaining, and contract administration. The topic of labor relations is often discussed within a very emotional atmosphere, and factual information can be minimal or absent. It is particularly important that management and supervisory staff understand the ramifications of their actions regarding personnel management within the context of unionization.

Union membership in the United States is at a historic low, with just above 14 million wage and salary employees belonging to unions in 2021 (10.3% of those employed). Combined, more than 1.4 million employees in healthcare support occupations or healthcare practitioner and technical occupations are members of unions (8.3% or 11.7% of total employees, respectively). Despite the increased number of employees in the healthcare and social assistance industry from 2020 to 2021 (17.858 million to 18.197 million), the percentage of union employees decreased from 7.1% to 6.6%, just above the overall private sector unionization rate of 6.1% in 2021 (Fig. 16.1) (2).

Labor Law

Current labor law supports workplace stability through collective bargaining and defined dispute resolution and can function to equalize the balance of bargaining power between employees and management. Since the Norris-LaGuardia Act in 1932, which declared a federal policy that employees could form unions, a number of laws have governed labor relations in the United States (3). These laws are generally divided into three categories, depending on the type of employee they cover (Table 16.1). The laws undergo

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch16.

本书版权归John Wiley & Sons Inc.所有

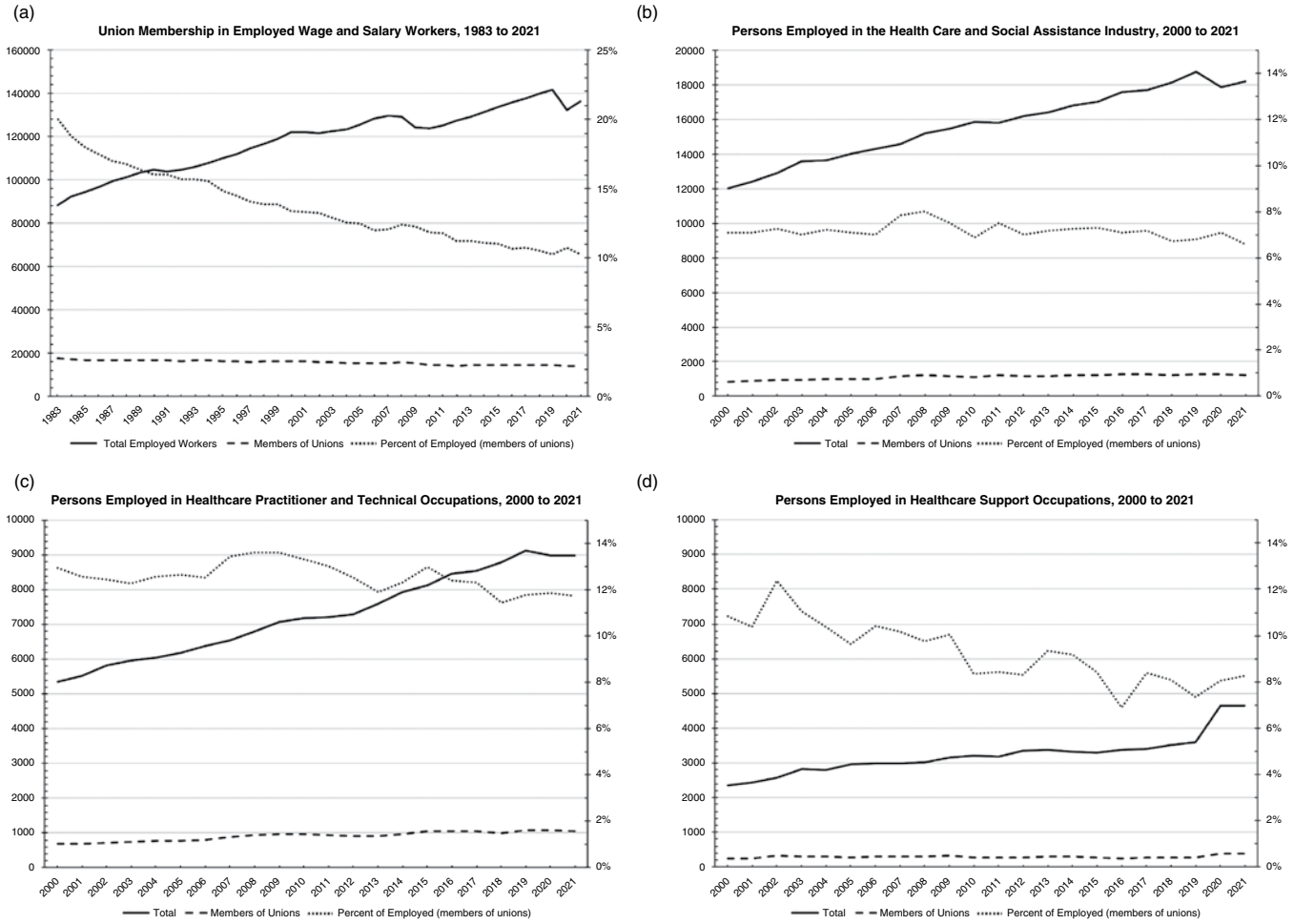


Figure 16.1 Total persons employed and union membership data in the healthcare field. (a) Union membership in all employed wage and salaried workers from 1983 to 2021. The percent union membership has declined or remained constant every year since 1983 with the exception of 2020, in which a 0.5% increase was observed. (b) Healthcare and social assistance industry union membership from 2000 to 2021 has largely remained stable at an average of 7.2%. (c) While the number of union employees in healthcare practitioner and technical occupations has increased over time (dashed line), the overall percentage of employees in unions has not. (d) The number and percent of union employees in healthcare support occupations increased in 2020 and 2021. Left Y-axis: person count (thousands); right Y-axis: percent of employed workers. Data from reference 2.

本书版权归John Wiley & Sons Inc.所有

Table 16.1 Labor law coverage for healthcare institutions and employees in the United States

Healthcare employees	Coverage
Federal government	1978: Civil Service Reform Act
State and local government	State labor laws
For-profit and nonprofit institutions	1935: National Labor Relations Act, as amended

constant review and modification based on changes to the actual laws and regulations, or agency and court decisions related to administration of the laws.

National Labor Relations Act (Wagner Act), 1935

Until the National Labor Relations Act (NLRA) of 1935, employers were not required to collectively bargain with unions. This legislation included some very important provisions: (i) Employees have the right to form, join, or assist unions; the freedom to bargain collectively with the employer; and the right to engage in group activity. (ii) Employers must bargain collectively with the employees' certified bargaining representative and must refrain from employer unfair labor practices. (iii) The National Labor Relations Board (NLRB) is the regulatory body responsible for administration of the NLRA.

Section 8 of the NLRA prohibits certain actions by the employer, identified as unfair labor practices (Table 16.2). Specific examples of employer discrimination include (i) discharging employees for urging other employees to join a union, (ii) refusing to reinstate an employee to an open job because the employee participated in a union strike related to an unfair labor practice or economics, (iii) refusing to hire a qualified applicant for a job because the applicant belongs to a union, and (iv) demoting employees for exercising their right to organize (4).

Fair Labor Standards Act (Black Act), 1938

More than 143 million workers in more than 7 million workplaces are protected by the Fair Labor Standards Act (FLSA), which is enforced by the Wage and Hour Division of the U.S. Department of Labor. Almost every employee in the United States is covered by the FLSA. Hours worked issues include waiting time, on-call time, meal and rest periods, training time, travel time, and sleep time. Covered, nonexempt employees must receive one and one-half times the regular rate of pay for all hours worked over 40 in a workweek. Exempt medical professions include doctors, registered nurses, and registered or certified medical technologists (3 years of preprofessional study in an accredited college or university, plus 1 year of professional study in an accredited school of medical technology) (5).

Some common FLSA violations include (i) misclassification of employees as being exempt from overtime, (ii) failure to pay for all hours an employee is permitted to work, (iii) failure to include all pay required to be included in calculating the regular rate for overtime, and (iv) failure to add all hours worked in separate sites for the same employer when calculating overtime due.

Table 16.2 Employer unfair labor practices that interfere with employee rights (NLRA)[a]

1. Interference with rights to unionize and to bargain collectively
   Threatening employees with loss of jobs or benefits
   Withholding customary periodic wage increases
   Offering increased wages or benefits to occur if and when the union loses the election
   Threatening to relocate or close the business
   Questioning employees about their union activities or membership under circumstances that would tend to restrain or coerce employees in their right to organize
   Spying on union gatherings or pretending to do so
   Granting wage increases timed to discourage employees from forming or joining a union
2. Domination of or contributing to a union
   Employer must remain neutral during the organizing process
   Employer cannot solicit employees to join a particular union or to oppose a competing union
   Employer cannot contribute financial or other support to the union
3. Discrimination against employees because of their union activities or because they filed charges or testified under the NLRA
   Transferring, laying off, terminating, or assigning employees more difficult work task or other punishment
4. Refusal to bargain in good faith with the employees' elected representatives

[a] Based on an NLRB report, unfair labor practice charges filed each year have been decreasing, from 19,280 in 2017 to 15,081 in 2021 (https://www.nlrb.gov/reports/nlrb-case-activity-reports/unfair-labor-practice-cases/intake/unfair-labor-practice-charges, accessed 21 April 2022).

Labor-Management Relations Act (Taft-Hartley Act)

An NLRA amendment, the Labor-Management Relations Act of 1947, addresses four problems that arose after passage of the NLRA in 1935, one of which was unfair labor practices by unions (Table 16.3). The Taft-Hartley Act guaranteed a broader interpretation of "free speech" for both the union and the employer, allowing both to express their views, arguments, and opinions. As long as these views are expressed without any threats of reprisal or promise of benefits, no unfair labor practice has been committed. Table 16.4 describes the five titles within this act.

The requirement for "good faith" bargaining by both the union and the employer is also a part of the Taft-Hartley Act; this includes meeting at reasonable times and places and conferring honestly regarding wages, hours, and other working conditions. However, there is nothing in the act that requires either the union or management to agree to concessions or proposals.

There are also notification guidelines if either the union or management wants to terminate or modify a contract upon expiration. Specific requirements include (i) a 60-day written notice prior to the expiration of the contract, (ii) an offer to meet and confer with the other party, (iii) notification to the Federal Mediation and Conciliation

本书版权归John Wiley & Sons Inc.所有

Table 16.3 Union unfair labor practices that interfere with employer rights (NLRA)

Refusing to bargain in good faith with the employer
Paying employees for work not actually performed
Charging discriminatory initiation fees or dues
Interfering with employees' choice of a labor union
Discriminating against certain employees and/or seeking the employer's discrimination against certain employees or potential employees (e.g., to discourage or encourage membership in a particular union)
Picketing, striking, and carrying out boycotts against businesses other than the employer involved in the primary labor dispute
Strikes or boycotts designed to make an employer assign work to a particular group to recognize a union without NLRB certification

Table 16.4 Titles within the Taft-Hartley Act (1947)

Title	Content
I	Amended NLRA (1935) Increased size of NLRB from three to five members (adjudicate cases) Established the Office of the General Counsel of the NLRB (supervises regional and field offices, investigates and prosecutes unfair labor practice charges) Granted employees right to form, join, or assist formation of union Granted employees right to bargain through representative of own choosing Granted employees right to engage in other protected activities for purpose of collective bargaining Outlined series of employer unfair labor practices, which violate employee rights.
II	Concerned with prevention of work stoppages (established FMCS) Outlined procedures by which president of the United States can obtain federal court injunction when strike or threatened strike endangers national welfare
III	Provided that suit to enforce labor-management contracts be brought in a federal district court
IV	Established a labor-management commission to study labor-management relations in the United States
V	Gave employees the right to refuse to work under abnormally dangerous conditions of employment without such a work stoppage being considered a strike

Service (FMCS) and any relevant state agency within 30 days of serving notice, and (iv) maintaining all terms and conditions of the contract for a period of 60 days after notice has been served or until the expiration date of the contract, whichever is later (6). These notification requirements for the healthcare industry are summarized in Table 16.5 and are based on the 1974 Healthcare Amendments (see below).

Labor-Management Reporting and Disclosure Act (Landrum-Griffin Act)

The Labor-Management Reporting and Disclosure Act of 1959 was passed to address some problems with the Taft-Hartley Act and to prevent abuses by union officials. The act prevents unions from restricting members regarding the right of free speech, assembly, and participation in union elections and meetings. Union officers are required to be bonded and accountable for union property and funds. The act also prevents dues from being increased without all members first voting by secret ballot.

Federal regulation for union internal operations is also addressed, including the NLRB supervision of union officer elections; minimum standards are in place for those wishing to be candidates for office, as well as for voting procedures. These include the following provisions: (i) All union members in good standing must be allowed to vote; (ii) elections for local officers must be held at least every 3 years; (iii) secret balloting procedures must be followed in local elections, but delegates to a national or international union convention may cast open votes; (iv) a reasonable opportunity to nominate candidates must be given to all eligible voting members; and (v) qualifications for candidate eligibility must be reasonable (7).

1974 Amendments to the NLRA

Prior to these amendments in 1974, nonprofit healthcare institutions were excluded from coverage by the NLRA; after passage of the amendments, nonprofit healthcare institutions were no longer grouped with employers excluded from the coverage of the act. A number of other features of the 1974 amendments involve the written notification rules described in Table 16.5. Notably, labor

Table 16.5 NLRA notice requirements in the healthcare industry (1974 Healthcare Amendments)

	Notice to:		
Notice type	**Other party**	**FMCS**	**Appropriate state agency**
Modify or terminate contract			
Initial bargaining	30 days	30 days	30 days
Existing contract	90 days	60 days	60 days
Notice of strike or picketing activity			
Initial bargaining	40 days: 10 days after the initial 30 days seen above	40 days: 10 days after the initial 30 days seen above	40 days: 10 days after the initial 30 days seen above
Existing contract	10 days	10 days	10 days

本书版权归John Wiley & Sons Inc.所有

organizations are required to give healthcare institutions a minimum of 10 days' advance written notice before they engage in a concerted refusal to work. In passing these amendments, Congress was very concerned about maintaining the continuity of patient care. If employees in a hospital setting are on strike and patients are transferred to another hospital, the ally doctrine does not apply; therefore, the striking employees from the first hospital cannot legally picket the second hospital (4).

Labor Law Updates

In the 1977 case, *Abood v. Detroit Board of Education*, the U.S. Supreme Court upheld against a First Amendment challenge a Michigan law that allowed public employers to collect union fees from employees who chose not to join the union, but who were represented by the union and benefited from the union's collective bargaining agreement (8). In June 2018, the U.S. Supreme Court held it is a violation of the First Amendment to require public sector employees who are not members of the union to pay any agency fees (*Janus v. AFSCME*, 2018) (9). As a result, unions representing government employees must now provide representation to all members of the bargaining unit, but cannot compel payment from those employees that are not members of the union. This ruling applies to only public sector unions (9). After the *Janus* case, multiple states considered legislation to reduce barriers to public sector unionization. In New York, introduced laws assure unions' access to new employees to discuss membership.

National Labor Relations Board (NLRB)

Description

The NLRB is an independent federal agency created by Congress in 1935 to administer the National Labor Relations Act, the primary law governing relations between unions and employers in the private sector. The statute guarantees the right of employees to organize and to bargain collectively with their employers, or to refrain from all such activity. Based on well-defined definitions, employers, employees, and labor unions understand the roles and expectations of each group.

Function

Based on its statutory duties, the NLRB has two main functions: (i) to determine through secret-ballot elections the free choice by employees whether they wish to be represented by a union in dealing with their employers and if so, by which union; and (ii) to prevent and remedy unlawful acts, called unfair labor practices, by either employers or unions. The agency does not act on its own in either function but processes only those charges of unfair labor practices and petitions for employee elections that are filed with the NLRB. The NLRB also resolves disputes about what constitutes an appropriate employee bargaining unit. Supervisors and managerial employees, as well as government workers and independent contractors, are not covered by the NLRA. Other groups not covered include municipal companies and religious schools. Although healthcare workers were previously exempted, most are now covered, provided they do not function as an independent contractor.

Structure

The agency has two major, separate sections: the board itself and the Office of the General Counsel. The board has five members and acts as a quasi-judicial body in deciding cases on the basis of formal records in administrative proceedings. NLRB members are appointed by the president to 5-year terms, with Senate consent, the term of one member expiring each year. The general counsel, appointed by the president to a 4-year term with Senate consent, is independent from the board members and handles the investigation and prosecution of unfair labor practice cases and the supervision of field offices in processing cases.

Processing of Cases

When an unfair labor practice charge is filed, the regional director investigates the charge to determine if there is reasonable cause to believe the NLRA has been violated. If the charge is determined to lack merit, it will be dismissed unless the charging party withdraws the charge. The dismissal of a charge can be appealed to the General Counsel.

If the regional director finds reasonable cause that the NLRA has been violated, the region seeks a voluntary settlement to remedy the alleged violations. However, if settlement efforts fail, a formal complaint is issued and the case goes to a hearing before an NLRB administrative law judge. The judge issues a written decision that may be appealed to the five-member board for a final agency ruling. This ruling is subject to review in a U.S. Court of Appeals and if necessary the U.S. Supreme Court (10).

While unfair labor practice charges have been declining since 2016, with only 15,081 charges filed in 2021, during the first 6 months of 2022, unfair labor practice charges increased 14% (7,255 to 8,254) compared to 2021 (11). It remains to be seen if this increase will continue for the entirety of 2022. Of the approximately 15,000 unfair labor practice charges filed each year, about one-third are found to have merit, of which over 90% are settled (12). In 2021, the board issued 243 decisions in contested cases, including 136 unfair labor practice cases and 107 representational cases (13).

Authority To Secure Injunctive Relief from a Court

The NLRB is able to petition a federal district court for an injunction to temporarily prevent unfair labor practices by employers or unions and to restore the status quo, pending

本书版权归John Wiley & Sons Inc.所有

the full review of the case by the board. In determining whether this action is appropriate in a particular case, the main question is whether injunctive relief is required to preserve the board's ability to remedy the unfair labor practice charge and whether the alleged violator would otherwise benefit from the violation. The act requires the board to seek a temporary federal court injunction against certain forms of union misconduct, mainly involving "secondary boycotts" and "recognitional picketing" (10).

Issues Related to the NLRB

As NLRB member appointments require agreement between both the president and the Senate, at times the NLRB has been short the required legal minimum of three members. In January 2012, President Barack Obama appointed three additional NLRB members during a Senate recess by invoking the Recess Appointments Clause, reaching the required quorum and restoring the board to the standard five members. However, a Court of Appeals for the D.C. Circuit held that the three 4 January 2012 recess appointments to the board were invalid, impacting as many as 600 prior NLRB decisions. In *NLRB v. Noel Canning*, the U.S. Supreme Court unanimously affirmed the 2012 recess appointments were unconstitutional, but refused to adopt the D.C. Circuit's reasoning that earlier recess appointments were improper as well. The NLRB was required to revisit decisions made between January 2012 and August 2013, when there was not a quorum of Senate-approved NLRB members (14).

Like the pendulum of a clock, new courses are charted in federal labor law as president-appointed members sway the focus of the NLRB. When President Donald Trump was in office, numerous decisions made during the Obama-era were overturned, including returning to the previous joint employer standard (see Hy-Brand Industrial Contractor, 365 NLRB No. 156) (15) and reversing the "micro unit" standard from the Specialty Healthcare and Rehabilitation Center of Mobile decision (357 NLRB No. 83) (16). It remains to be seen how the NLRB will influence labor law during the tenure of President Joe Biden; the self-proclaimed pro-union president broke with tradition by replacing Trump-appointed General Counsel Peter Robb within hours of taking office (17, 18).

Union Structure

Formal Structure

The majority of national unions in the United States belong to the voluntary federation, the American Federation of Labor–Congress of Industrial Organizations (AFL-CIO). The AFL-CIO provides research, education, lobbying, and public relations activities for its unions; it does not get involved with the internal affairs of its member unions. The individual unions are autonomous regarding strikes, contract demands, and internal affairs.

Usually, local unions are subunits of the national unions. However, in the absence of a national union, a local union may form to bargain with one or more employers. Generally, local unions vary considerably in size and may range from fewer than 10 members to more than 40,000.

Each union has a constitution that is on file with the Secretary of Labor; the content specifies the titles and duties of the officers, normally including elected officers such as president, vice-president, business manager, treasurer, financial secretary, recording secretary, and grievance committee chair. Some of these positions may be full-time paid officers, while others are volunteers and are reimbursed for out-of-pocket expenses and work time lost while conducting union business.

Union Membership

In 2021, union membership declined by 241,000 wage and salary workers, marking the lowest total union members to date at just over 14 million (2). While 2021 tied 2019 as the year with the lowest percent of union membership (10.3%), a brief increase to 10.8% occurred in 2020 (Fig. 16.1a), likely the consequence of the emergence of a novel human pathogen in December 2019, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). As of October 2023, over 770 million cases of COVID-19, the disease caused by SARS-CoV-2, have been reported worldwide. Of the almost 7 million deaths attributed to COVID-19, over 1 million deaths have occurred in the United States (19).

During the first year of the COVID-19 pandemic, the total employed in the private sector decreased by over 7.4 million workers (2019 to 2020). Industries less likely to be unionized, such as leisure and hospitality, lost a larger number and percentage of their workforce than industries such as healthcare and social assistance (2.97 million workers lost in 2020, 22% of the 2019 leisure and hospitality workforce; 914,000 workers lost in healthcare industry, 4.8% of the 2019 workforce). Job loss at higher rates in less unionized industries contributed to the increased unionization rate in 2020. As the economy recovered in 2021 and jobs restored, this dynamic has reversed (Fig. 16.1a) (2). Other 2021 union membership data can be found in Table 16.6.

The increased visibility of strikes and walkouts during the COVID-19 pandemic is likely reflected in recent polls regarding support for unions. A 2021 Gallup poll showed 68% of respondents approved of labor unions, the highest percentage since 1965 (20). Additionally, decreasing union membership may not accurately reflect worker feelings toward unionization. A survey conducted at the MIT Sloan School of Management in 2017 found 48% of nonunionized

本书版权归John Wiley & Sons Inc.所有

Table 16.6 2021 union membership data[a]

Men (10.6%) (11.0% in 2020) were more likely to be union members than women (9.9%) (10.5% in 2020)
Union membership for blacks (11.5%) (12.3% in 2020) remained higher than the rates for whites (10.3%) (10.7% in 2020), Hispanics (9.0%) (9.8% in 2020), and Asians (7.7%) (8.9% in 2020)
Public-sector workers had a union membership rate of 33.9%, more than five times the 6.1% rate of union workers in private-sector industries
The highest unionization rates were in the education, training, and library occupations (34.6%), followed by the protective service occupations (33.3%); the latter include firefighters and police officers
About 1.79 million wage and salary workers were represented by a union, while not being union members themselves (up from 1.69 million in 2020)
Hawaii (22.4%), New York (22.2%), and Washington (19.0%) had the highest union membership rates, while 10 states had rates below 5%, with the lowest rate in South Carolina (1.7%)
The largest numbers of union members live in California (2.47 million), New York (1.73 million), and Illinois (752,000)
Between 2020 and 2021, 15 states increased the percentage of union employees, while 34 states saw decreased union membership rates

[a] From reference 2.

American workers answered they would join a union if given the opportunity (21). In further support, union representation petitions filed at the NLRB have increased 57% in the first 6 months of fiscal year (FY) 2022, compared to FY2021; FY2021 had the lowest representation petitions filed in the past decade, with only 862 elections held (22). More time will be needed to know if the COVID-19 pandemic will have lasting effects on union membership.

Unions that are active within the healthcare environment include Service Employees International Union (SEIU); the Committee of Interns and Residents (CIR); National Union of Hospital and Health Care Workers; American Federation of State, County, and Municipal Employees (AFSCME); Office & Professional Employees International Union (OPEIU); International Federation of Professional and Technical Engineers (IFPTE); United Food and Commercial Workers (UFCW); the American Federation of Government Employees; National Nurses United (NNU); and the American Nurses Association.

Function of the Union Steward

One of the most important positions in any union is the steward; this position is comparable to one of the levels in management (7). The steward listens to grievances by employees in the bargaining unit, counsels them on a course of action, and depending on the circumstances, intercedes with management on their behalf. Reasons for grievances might include discipline, failure to get a merit increase or promotion, and disagreement with the employer evaluation process. A part of the steward's responsibility is to review all the evidence related to grievances and to obtain a factual account from both the employee and management regarding the issues involved. Generally, a union steward will not defend inappropriate employee behavior, particularly if this approach would result in a loss of credibility with the employer, a situation that would complicate future contract negotiations. In many collective bargaining agreements, the initial grievance must be presented to the employee's immediate supervisor as the first step; employees may ask for assistance from the steward at this beginning step in the process. The Supreme Court has ruled that a member of the bargaining unit has a right to union representation during a management interview if the employee feels that disciplinary action might result from the interview (23).

Unionization Process

Individual, Group, and Union Image: Reasons Why Employees Join a Union

Although there may be a number of reasons why employees decide to join unions, generally these reasons can be categorized as (i) personal, (ii) related to the social environment, or (iii) related to the image of the union. Physicians must consider additional factors prior to agreeing to union membership, first and foremost how union action could impact patient care. Furthermore, pathologists or physician groups that are independent contractors with regard to insurance company negotiations may not be qualified to join a union. During the COVID-19 pandemic, the combination of economic, health, and safety concerns pushed many employees to reconsider unionization, with notable efforts taking place at specific locations of large corporations. Table 16.7 highlights reasons employees may seek representation.

Relevance for Healthcare Workers

Employment in healthcare is projected to grow by 16%, an estimated 2.6 million jobs, between 2020 and 2030 (24). In 2021, 9,005,000 people (6.6% of the total, 136,393,000) were employed as healthcare practitioners or in technical occupations, down from 6.8% in 2020. While the number of unionized employees in these occupations, which includes clinical laboratory technologists and technicians, has remained relatively stable since 2015, the number of persons employed in healthcare support occupations has increased in both 2020 and 2021 (2). Overall, of the >18 million employees in the healthcare and social assistance industry, 1.2 million were represented by unions, a 0.5% decrease in unionization percentage from 2020 (Fig. 16.1) (2).

For many years, healthcare professionals as a group have been somewhat skeptical and apprehensive about unionization, with many assuming they would never need to join a union. However, professional workers are confronting increasing challenges to their careers. From overflowing

本书版权归John Wiley & Sons Inc.所有

Table 16.7 Reasons why employees decide to seek union representation

Personal reasons	Social environment	Image of the union
Individual	Family tradition and history	Success in bargaining
Economic benefits (salary, fringe benefits)	Work-category tradition and history	Ability to represent workers
Job security	Unionization within the organization and/or community	Goals consistent with individual goals
Fairness in job conflict resolution	Unionization within the profession, pros/cons	Ability to support and advance the profession
Health and safety concerns	Based on work group union membership, pressure to conform to the group	Professional in their approach to labor relations
Group		Reasonable dues
Unity and togetherness		No evidence of violence
Advancement of profession		
Staffing		

emergency departments to shortages of personal protective equipment, healthcare workers are feeling increasingly physically and mentally exhausted amid safe staffing ratios concerns, mandatory overtime, and other stressors of the COVID-19 pandemic. A 2021 study of over 20,000 U.S. healthcare workers found almost half experienced burnout from May to October 2020 (25). While a cross-sectional survey study that evaluated the association of resident unions with well-being found unions did not impact resident physician burnout (26), union membership did increase other work benefits including vacation time and housing stipend offerings. As the healthcare field continues to grow, more workers may begin to consider union membership (27).

Organizing Campaign

The first step in the process of gaining union representation is the organizing campaign. Employees may contact a union representative to initiate a discussion or union representatives may initiate the contact to determine whether employees want to pursue discussions about possible unionization. Employees' right to seek or aid unionization, or to refrain from such activities, is guaranteed by the NLRA. There may be more than one union involved in an organizing campaign, competing for the employees' interest and eventual votes for union representation. How the organizing campaign is handled will impact relations with employees for years to come, regardless of the outcome, and all parties involved should avoid inappropriate behavior that can lead to feelings of betrayal and mistrust.

Authorization Cards

It is highly unlikely that management will voluntarily recognize employees' wishes to be represented by a union for the purposes of collective bargaining. During the COVID-19 pandemic, a supermajority of house staff physicians at some institutions requested to be represented by the union CIR/SEIU; however, management at both institutions declined to voluntarily recognize the union (28). In cases such as these, the union must follow set procedures from the NLRB to demonstrate employee interest. The union will ask employees to sign authorization cards stating that the employee wishes to be represented for purposes of collective bargaining by the union named on the cards. The union must have 30% of the employees sign authorization cards before the NLRB will honor a petition for a union-representation election. The union must specify in its petition exactly which occupational groups it seeks to represent; this specification begins the process of defining the bargaining unit.

The Bargaining Unit

Final responsibility for determining the job categories within a bargaining unit resides with the NLRB, which will consider the pros and cons of inclusion and exclusion of various groups as requested by the union and the employer. The employer may challenge the union's proposed bargaining unit and may wish to include occupational groups perceived to be unfavorable toward unionization or may want to decrease the bargaining unit to eliminate groups perceived to be in favor of unionization. Key factors considered by the NLRB include (i) the history of bargaining within the industry and occupational groups under consideration, (ii) the community of interest among employees and common supervision, and (iii) the wishes of the employees. In December 2021, the NLRB invited briefs addressing whether the board should reconsider the standard for determining if a proposed bargaining unit is appropriate (29). In general, the NLRB will allow the following bargaining units in a healthcare institution: physicians, registered nurses, other professional employees, technical employees, service and maintenance employees, and business office clerical employees.

Information Distribution and Solicitation

Information distribution generally refers to distribution of printed materials to employees, in which the content is informational only. Solicitation is directed to a specific individual, with the intent to elicit a specific response from that individual; an excellent example is the request

本书版权归John Wiley & Sons Inc.所有

Table 16.8 Rulings regarding information distribution and solicitation in the hospital setting

Union	Distribution and solicitation by an employee (pro-union) are allowed during nonworking time in nonworking areas of other nonworking employees on the premises other than patient care areas (patient rooms, operating rooms, treatment rooms)
Union	Solicitation is banned in sitting rooms and corridors adjoining or accessible to patient rooms; crowding issues
Employer	Cannot ban solicitation in the cafeteria, gift shop, and lobbies on the first floor of the institution; however, employer need only show that solicitation is likely to disrupt patient care or disturb patients in order to enforce a ban on solicitation in non–patient care areas
Employer	May allow solicitation in "normal gathering places" for employees, but ban it in certain areas such as lobbies and gift shops
Employer	If management insists on a very broad "no solicitation rule," it is important that supervisors and managers realize this approach may be found to be invalid if challenged by the union

for an employee to sign and return an authorization card, mentioned earlier in this discussion. There are very specific rules that govern these activities, both for the union and for the employer. Table 16.8 shows several specific examples. It is important that a proper balance be achieved between the rights of the employees and the rights of management to guarantee safe and efficient patient care.

Election

Once at least 30% of the employees in a proposed bargaining unit have signed and turned in authorization cards, the union may petition the NLRB for a representation election. There is a time lag between the submission of the petition for election and the election itself; during this interim, management will campaign vigorously to counteract the union's position and will try to change employees' minds regarding the necessity for unionization. Signing an authorization card does not require the employee to vote (for or against the union) in the representation election. The NLRB, or in the case of federal workers the Federal Labor Relations Authority, reviews the petition and makes a number of determinations directly related to approval or rejection of the election proposal.

If there are no reasons to preclude the election, and the bargaining unit is appropriate, agreement is sought regarding a "consent" election. If either the employer or the union(s), or both, fail to agree to a consent election, a formal hearing occurs before a hearing officer appointed by the regional director. Although the regional director makes the decision, either ordering the election to occur or dismissing the petition, a party may appeal the decision to the NLRB (10). If all parties agree to the consent election based on the filing of the petition, the date is set, and the election normally occurs 60 days after the union files the petition. However, if the parties do not agree and the hearing process is instituted, the election normally occurs between 25 and 30 days following the final decision.

Employees who have been confirmed as being in the bargaining unit at the end of the payroll period immediately preceding the date of the election are eligible to vote. The employer must provide the NLRB and the union a list of names and contact information of eligible employees within 5 business days after the final decision on the consent election. The election is held at a place and time that are designed to provide maximum participation for all bargaining unit employees; mail ballots may also be used in the election process. The election is by secret ballot, and the union must have a simple majority of the votes cast to win and to be certified by the NLRB as the bargaining representative.

All relevant parties may have observers at the polls; an NLRB agent supervises the observers to ensure appropriate behavior during the election process. Ballots may be challenged, and these ballots are impounded. If the number of impounded ballots would make a difference in the election outcome, the NLRB regional office investigates these ballots and decides whether or not they will be counted. If the number of impounded ballots will not impact the election outcome, they are not counted. Depending on the ballot count, there may need to be a runoff election; this occurs if more than one union is involved in the election process and there is no majority vote for one union or for no representation.

Certification

If union representation is rejected, another election within that bargaining unit cannot be held for 12 months. If a union wins the election, the NLRB issues a certification of representative confirming the union's status as the exclusive bargaining representative for a period of 1 year after the date of certification. During this 1-year period, the employer is required to bargain with the certified union. It is important to remember that although the bargaining unit may be composed of union members and those who choose not to join the union, a negotiated collective bargaining agreement applies to all those within the bargaining unit. Because compulsory union membership is prohibited but all members of the bargaining unit benefit from union representation, some states allow private sector unions to collect some portion of the monthly union dues from nonunion members of the bargaining unit; this practice is not allowed in public sector unions (9). A review of the organizing, election, and certification phases of the process can be seen in Fig. 16.2.

本书版权归John Wiley & Sons Inc.所有

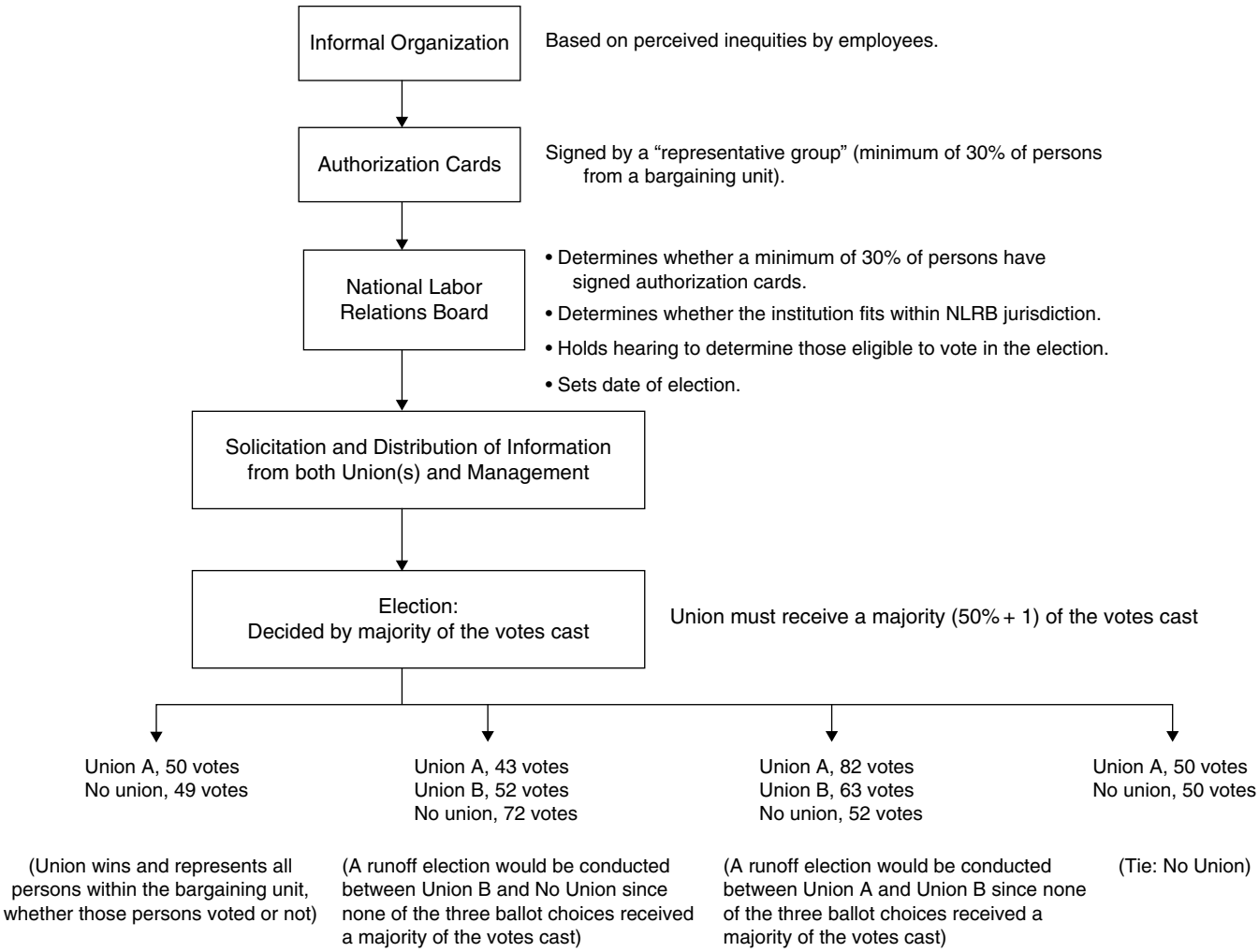


Figure 16.2 Union organizing campaign from first inquiries to election results.

Collective Bargaining

After a bargaining unit selects a particular union as its representative, both the employer and the union must bargain in good faith. This negotiating process addresses many issues, such as (i) establishing work rules, (ii) selecting the form and mix of employee compensation, (iii) providing uniformity among competitors, and (iv) setting priorities for both labor and management.

Issues for Bargaining

There are three basic categories of bargaining subjects: mandatory, permissive, and illegal and prohibited (2). Mandatory subjects include wages, hours, and other terms and conditions of employment. Permissive subjects are bargained only if both parties voluntarily agree to do so. However, neither party may refuse to bargain on mandatory subjects to force bargaining on permissive subjects. Illegal or prohibited subjects include those that would cause one or both parties to violate federal or state law, such as (i) bargaining for a closed shop, (ii) bargaining for a contract clause under which union members could refuse to work with nonunion goods and materials, and (iii) bargaining for contract language that would permit discrimination as defined by the Civil Rights Act. Attempts to negotiate these illegal subjects would constitute an unfair labor practice (ULP). Other unfair labor practices associated with the bargaining process include (i) refusing to bargain collectively, (ii) failing to offer meaningful counterproposals, (iii) refusing to discuss economic terms until noneconomic issues are resolved, and (iv) attempting to delay meetings or move meeting sites. Although the NLRB cannot force an agreement between the parties, as a remedy for an unfair labor practice, the Board can order them to bargain or may issue a cease and desist order to refrain from bad faith bargaining.

Preparation Phase

The union and the employer begin the process by selecting negotiating teams. The union team is often led by a full-time paid official, while the management team is led by

本书版权归John Wiley & Sons Inc.所有

industrial relations managers and key department managers. Both parties may also include attorneys experienced in labor law and contract negotiations. Depending on the size and complexity of the bargaining units and relevant issues, preparations by both negotiating teams may begin several months prior to actual negotiations or may begin as long as a year prior to initiation of the bargaining process.

Negotiation Phase

Table 16.9 shows a representative list of bargaining subjects. It is important to remember that almost any topic falling within the context of wages, hours of work, and other terms and conditions of employment is a mandatory bargaining subject. Some issues may be bargained to the point of impasse but not lead to a work stoppage if the union feels they are not issues about which members feel strongly. Some contracts allow either party to reopen negotiations on any section of the contract by giving the other party a notice of such interest. A change may also be accomplished by amending the contract through a letter of agreement covering a specific issue.

Administration of the Agreement

Unfortunately, there is no such thing as a "perfect" contract. The negotiating teams cannot envision all the potential problems that could arise during the time span of the contract. Different people will interpret the contract differently, especially depending on healthcare environmental changes, economic conditions, and a number of other potential changes. If the union, the employer, or an employee believes that the collective bargaining agreement has been violated, the process for handling such disagreements is contract administration, which uses the agreement's grievance procedure, which likely contains arbitration as the final step. The purpose of such a process is to provide a mechanism for handling day-to-day differences among the union, management, and employees.

The grievance procedure includes a series of steps through which the complaint may move toward resolution. The initial step usually includes a verbal discussion with the opposite party. Each step contains time limits for the appeal and response after the preliminary discussions. Each step in the process also includes the addition of higher levels of decision makers. If resolution is not obtained, most collective bargaining agreements provide that either the union or the employer, but not an aggrieved employee, may appeal to arbitration; usually 60 to 120 days elapse before a grievance reaches arbitration. During arbitration, a neutral third party, or arbitrator, hears the facts and each party's position. The arbitrator then renders a final and binding decision. These arbitrators are selected and agreed upon by both parties prior to the beginning of the arbitration process. The arbitration hearing is similar to a court hearing; witnesses are called and subjected to cross-examination, exhibits are introduced, and the opposing parties present opening and closing arguments. However, there is no jury. Although a single individual conducts most arbitration hearings, an arbitration panel may be used.

Table 16.9 Representative topics for contract negotiations

Recognition and representation
Membership requirements
Wage rates (including cost-of-living clause)
Hours and overtime
Flextime options, including four days on, four days off, etc.
Shift differentials
Seniority
Vacations
Personal leave and provisions for time off
Holiday, overtime, on-call, "incentive," and merit pay
Lunch and rest periods
Employee benefits (e.g., insurance, pensions)
Safety and health
Grievance procedure
Corrective action and discharge procedure
Strikes and lockouts
Effect of agreement and amendments
Use of bulletin boards
Management rights
Union security clause
Dues "checkoff" clause
Terms of the contract

Management Rights Clause

Although the length of this clause in the contract may vary from several paragraphs to several pages, the management rights clause generally states that management has the sole right and prerogative to unilaterally make decisions concerning the operation of the institution except as it may be limited by the contract (30). These rights include the right to hire, fire, suspend, and discharge for just cause; to temporarily assign, promote, or discharge employees according to the needs of the business; to determine the methods of work; and other items. The inclusion of the management rights clause can often eliminate prolonged disagreement over many issues, one of which is the right to suspend and discharge employees for just cause. These policies must be clearly defined and consistently used. Often the union may challenge a suspension or discharge for lack of just cause. The arbitrator may reinstate an employee who has been improperly terminated. The arbitrator may also decide on remedial action, such as full pay for all time lost and restoration of all benefits that resulted from improper discharge. Due to the potential for lengthy remediation of such issues, many contracts include provisions for an

本书版权归John Wiley & Sons Inc.所有

expedited grievance procedure, thus limiting the potential for substantial remedial legal liability.

Labor Actions and Disputes

The right to strike is guaranteed in Section 7 of the NLRA; however, the lawfulness of a strike will depend on the purpose of the strike, its timing, and the conduct of the strikers. The NLRB determines lawfulness, along with questions regarding back pay and reinstatement. Lawful strikers fall into two classes, economic strikers and unfair labor practice strikers, with employees in the latter group having greater rights of reinstatement. Economic strikers' goal is an economic concession, such as higher wages, shorter hours, or better working conditions. They cannot be discharged or replaced by their employer as they retain their employee status; however, if the employer has hired bona fide, permanent replacement employees when the strikers apply unconditionally to go back to work, the strikers may not be entitled to reinstatement. In contrast, unfair labor practice strikers can neither be discharged nor permanently replaced absent serious misconduct on their part (4, 31).

While the U.S. Bureau of Labor Statistics (BLS) documents actions involving 1,000 or more workers that last at least one shift, the Cornell University ILR Labor Action Tracker, started in 2021, records work stoppages regardless of size. According to the Labor Action Tracker 2021 Annual Report, 34 of the 265 documented work stoppages in 2021 occurred in the healthcare and social assistance industry, with only 24 total stoppages involving 1,000 or more employees (32). Of the two-thirds of work stoppages that involved union workers reported by the Labor Action Tracker, only 82.7% were union authorized. In 2021, the BLS recorded 16 major work stoppages involving 80,700 workers, of which 45,400 were healthcare and social assistance workers (33). Of the reasons driving work stoppages in 2021, the top five were pay, healthcare, health and safety, staffing, and COVID-19 protocols (32).

SUMMARY

Contemporary labor law attempts to balance two goals: the encouragement of stability through collective bargaining and reasonable dispute settlement and the balance of bargaining power between employees and management. The COVID-19 pandemic has highlighted labor relations across numerous industries, including healthcare. Therefore, it is critical that all levels of management personnel recognize the importance of understanding labor relations, both as a general concept and as a complex process with many parts. Also, all of the systems inherent in labor relations must be seen as dynamic, changing entities, primarily based on changes in the laws themselves, changes in the regulations, decisions of agencies participating in the administration of the laws, and the decisions of the federal and state courts.

KEY POINTS

- Labor law is continuously evolving to ensure the balance of power between employees and employers.
- The unionization process is very clearly defined, with specific actions that can and cannot be taken by all parties involved.
- Specific legal entities support, guide, and confirm appropriate behavior by unions, employers, and employees.
- Through the organizing campaign, election, and certification process a union may or may not be voted in as the exclusive representative of a particular bargaining unit.
- Collective bargaining comprises mandatory, permissive, and illegal topics for negotiation.
- Although some contracts are very detailed and inclusive, there is no such thing as the "perfect" contract. Therefore, the ability to administer the contract specifications can require a day-to-day working knowledge of the contract and its use.
- The percent of employed wage and salary workers represented by unions has continued to decline from a peak of 34.8% in 1954 to a low of 11.6% in 2021. However, the impacts of the COVID-19 pandemic on unionization are not yet fully realized.

GLOSSARY

Administrative law judge The National Labor Relations Board (NLRB) has a corps of judges who work for them and conduct hearings at which the parties present evidence. Decisions of administrative law judges can be appealed to the five-member Board in Washington, DC.

AFL-CIO American Federation of Labor–Congress of Industrial Organizations; voluntary federation of unions that provides education, lobbying, public relations, and consultation services for unions; currently has 57 member unions covering more than 12.5 million employees.

Ally doctrine Acceptance of work normally performed by striking employees of a struck employer by a neutral employer; thus the neutral employer becomes an "ally" of the struck employer; the neutral or ally employer may be legally picketed by the striking employees of another employer; the ally doctrine does not apply in healthcare settings (example: hospital).

Arbitration A process during which a neutral third party decides the outcome of a dispute between labor and management, typically regarding a collective bargaining agreement. The arbitrator then issues a decision, which is binding on the parties.

Authorization card A card that authorizes the union to represent the employee during the collective bargaining process once the card is signed by the employee.

本书版权归John Wiley & Sons Inc.所有

Authorization card, required percentage The union must obtain authorization cards from at least 30% of the employees in a bargaining unit as proof of "employee interest" before the NLRB will allow an election for union representation.

Bargaining topics Include wages, hours, and conditions of employment; neither labor nor management can refuse to bargain on these issues.

Bargaining unit A group of employees (approved by the NLRB) that share a community of interest and can vote in a union representation election; they will be the group represented by the union and are covered by the terms of the collective bargaining agreement if the union wins the election and negotiates a contract with the employer.

Bargaining unit, employees Usually composed of a family of closely associated jobs.

Certification election Conducted by the NLRB to determine whether employees do or do not want to be represented by the union that wants to represent them.

Certified union Has the exclusive right to bargain on behalf of the employees it represents; individual employees within the represented group are not allowed to enter into separate agreements with the employer.

Charge An allegation made by an individual, employer, or labor organization of an unfair labor practice (ULP) under the National Labor Relations Act (NLRA); charges are filed at the NLRB's regional offices.

Closed shop Illegal; an employment site where all employees must join the union prior to employment.

Collective bargaining Contract negotiations between union and employer; mandatory topics include wages, hours, and conditions of employment. Collective bargaining is governed by federal and state statutory laws, administrative agency regulations, and judicial decisions; in areas where federal and state law overlap, state laws are preempted.

Complaint After investigating a ULP charge, if the regional office finds merit and no settlement is reached, the regional director of the NLRB issues a complaint in the name of the Board stating the unfair labor practices and containing a notice of hearing before an administrative law judge. The complaint does not constitute a finding of wrongdoing but raises issues to be decided by the judge.

Decertification An election in which bargaining-unit employees vote to rescind the union's certification as their representative.

Decertification requirement Petition for decertification election requires a minimum of 30% of the employees within the bargaining unit.

Dues Paid by the union members, usually on a monthly basis; with employee-signed authorization, can be paid through automatic payroll deduction.

Election (NLRB) Election process for union representation with a secret-ballot election at the work site, including voting booths and ballot boxes; overseen by an NLRB agent in a space where the employee and union are not present during the balloting process.

Federal Mediation and Conciliation Service (FMCS) Federal agency that provides mediation services to labor and management to resolve bargaining impasse situations or to assist in securing arbitrators.

Full-time workers Workers who usually work 35 hours or more per week at their sole or main job.

Good faith bargaining To bargain collectively is the mutual obligation of the employer and the representative of the employees. Both parties agree to meet at reasonable times and confer in good faith with respect to wages, hours, and other terms and conditions of employment, the negotiation of an agreement or any question arising thereunder, and the execution of a written contract incorporating any agreement reached if requested by either party. This obligation does not compel either party to agree to a proposal or require the making of a concession.

Grievance Allegation, typically by a union or bargaining unit employee, that the employer has acted improperly, usually by violating provision(s) of the collective bargaining agreement.

Impasse A deadlock in negotiating between management and union over terms and conditions of employment. According to the NLRB, whether an impasse in bargaining exists "is a matter of judgment" and depends on such factors as "bargaining history, the good faith of the parties in negotiations, the length of the negotiations, the importance of the issue or issues as to which there is disagreement, the contemporaneous understanding of the parties as to the state of negotiations."

Labor laws, agency:

1935: National Labor Relations Act (Wagner Act) Federal law passed in 1935; gives employees the right to organize, select their representative(s), and bargain with the employer regarding wages, hours, and working conditions; established the authority of the NLRB.

1938 Fair Labor Standards Act (Black Act) Federal law passed in 1938 that establishes minimum wage, overtime pay, record keeping, and youth employment standards affecting employees in the private sector and in federal, state, and local governments.

1947: Labor-Management Relations Act (Taft-Hartley Act) Federal law passed in 1947; amended the National Labor Relations Act and established the authority of the Federal Mediation and Conciliation Service.

1959: Labor-Management Reporting and Disclosure Act (Landrum-Griffin Act) Designed to close loopholes in the Taft-Hartley Act pertaining to internal union affairs; provides amendments to the National Labor Relations Act.

1974: Amendments to the NLRA Provides NLRA notice requirements in the healthcare industry.

1978: Civil Service Reform Act Established the Federal Labor Relations Authority (FLRA) for administration of federal sector labor relations.

Lockout When the employer closes the business or dismisses employees in order to deny current employees access to the workplace.

本书版权归John Wiley & Sons Inc.所有

Management rights clause Contract clause in a bargaining agreement that states that anything not covered in the contract remains within the purview of management.

Managerial "employee" Persons who provide managerial functions are not employees and are excluded from protection under the National Labor Relations Act (NLRA).

Medicaid A federal health program for low-income adults, their children, and people with certain disabilities. It is jointly funded by the state and federal governments but is managed by the states.

Medicare A federal health program for people aged 65 or older and younger people with certain disabilities. Those enrolled in the program must pay deductibles and copayments. Medicare is divided into four parts: Part A covers hospital bills, Part B covers doctor bills, Part C provides the option to choose from a group of healthcare plans, and Part D provides prescription drug coverage.

No-solicitation rule Rule instituted by management to prevent solicitation of employees for union membership at the workplace. Rules that are too broad are often found to be invalid by the NLRB and the courts.

No-strike, no-lockout clause During the life of the contract, a clause in which the union agrees not to strike and management agrees not to lock employees out or keep them from reporting to work.

Part-time workers Workers who usually work less than 35 hours per week at their sole or main job.

Professional employees Employees meeting the NLRA (amended) criteria; generally professionals and nonprofessionals are not included in the same bargaining unit.

Represented by unions Employees who may or may not be union members but whose jobs are part of a bargaining unit represented by a union.

Steward Individual within a union who serves as the union's counterpart of the employer's manager or supervisor.

Unfair labor practice (employers) Interference with employee rights to organize, join, or assist a labor organization.

Unfair labor practice (labor organizations) Restraining or coercing the employer or employees as they exercise their legal rights, or action reasonably calculated to do so.

Union shop A site where all employees must join the union after a short introductory period.

REFERENCES

1. **Karni KR**, **Viskochil KR**, **Amos PA**. 1982. *Clinical Laboratory Management*, p 519–553. Little, Brown and Co, Boston, MA.

2. **U.S. Bureau of Labor Statistics**. 2022. Union Members Summary. U.S. Department of Labor. https://www.bls.gov/news.release/union2.nr0.htm. Accessed 2 April 2022.

3. **Emerson RW**, **Haardwicke JW**. 1987. *Business Law*, 3rd ed. Barron's Educational Series, Inc., Hauppauge, NY.

4. **National Labor Relations Board**. 1997. Basic guide to the National Labor Relations Act, rev ed. Office of the General Counsel, Washington, DC. https://www.nlrb.gov/guidance/key-reference-materials/national-labor-relations-act. Accessed 19 October 2023.

5. **Wage and Hour Division**. 2014. Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Computer and Outside Sales Employees—Fair Labor Standards Act. 29 CFR Part 541. https://www.ecfr.gov/current/title-29/subtitle-B/chapter-V/subchapter-A/part-541. Accessed 19 October 2023.

6. **Bakke EW**. 1960. *Unions, Management, and the Public*, 2nd ed. Harcourt, New York.

7. **Office of Labor-Management Standards**. 2017. Electing Union Officers. U.S. Department of Labor. https://www.dol.gov/agencies/olms/compliance-assistance/elections. Accessed 6 October 2023.

8. 1977. *D. Louis Abood et al., v Detroit Board of Education et al*, vol 431, p 209. U.S. Supreme Court.

9. 2018. *Janus v. American Federation of State, County, and Municipal Employees, Council 31, et al.*, vol 585. U.S. Supreme Court.

10. **National Labor Relations Board**. 2022. The NLRB Process. http://www.nlrb.gov. Accessed 2 April 2022.

11. **Office of Public Affairs**. 2022. Union Election Petitions Increase 57% in First Half of Fiscal Year 2022. National Labor Relations Board. https://www.nlrb.gov/news-outreach/news-story/union-election-petitions-increase-57-in-first-half-of-fiscal-year-2022. Accessed 19 October 2023.

12. **National Labor Relations Board**. 2022. Unfair labor practice charges filed each year. https://www.nlrb.gov/reports/nlrb-case-activity-reports/unfair-labor-practice-cases/intake/unfair-labor-practice-charges. Accessed 5 April 2022.

13. **Office of Public Affairs.** 2021. The NLRB Reduces the Median Age of Pending Cases by 15% in Fiscal Year 2021. National Labor Relations Board. https://www.nlrb.gov/news-outreach/news-story/the-nlrb-reduces-the-median-age-of-pending-cases-by-15-in-fiscal-year-2021. Accessed 19 October 2023.

14. 2014. *National Labor Relations Board v. Noel Canning et al.*, vol 573, p 513. U.S. Supreme Court.

15. **Office of Public Affairs**. 2018. Board Vacates Hy-Brand Decision. National Labor Relations Board. https://www.nlrb.gov/news-outreach/news-story/board-vacates-hy-brand-decision. Accessed 19 October 2023.

16. **Office of Public Affairs**. 2017. Board Overrules Specialty Healthcare, Eliminates "Overwhelming Community of Interest" Standard. National Labor Relations Board. https://www.nlrb.gov/news-outreach/news-story/board-overrules-specialty-healthcare-eliminates-overwhelming-community-of. Accessed 19 October 2023.

17. 2021. Remarks by President Biden in Honor of Labor Unions. The White House. https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/08/remarks-by-president-biden-in-honor-of-labor-unions/. Accessed 19 August 2022.

18. **Office of Public Affairs**. 2022. Fifth Circuit Court of Appeals Rejects Argument that President's Removal of Former NLRB General Counsel Was Improper, Upholding Validity of NLRB Complaint. National Labor Relations Board. https://www.nlrb.gov/

本书版权归John Wiley & Sons Inc.所有

news-outreach/news-story/fifth-circuit-court-of-appeals-rejects-argument-that-presidents-removal-of. Accessed 19 October 2023.

19. **World Health Organization**. 2022. WHO coronavirus (COVID-19) dashboard. https://covid19.who.int/. Accessed 19 October 2023.

20. **Gallup**. 2021. Labor Unions. https://news.gallup.com/poll/12751/labor-unions.aspx. Accessed 22 April 2022.

21. **Kochan TA, Yang D, Kimball WT, Kelly EL**. 2019. Worker voice in America: is there a gap between what workers expect and what they experience? *Ind Labor Relat Rev* **72**:3–38.

22. **National Labor Relations Board**. 2022. Representative Election PetitionsFiled.https://www.nlrb.gov/about-nlrb/what-we-do/conduct-elections. Accessed 19 October 2023.

23. 1975. *NLRB v J. Weingarten Inc*., vol 420, p 251. U.S. Supreme Court.

24. **U.S. Bureau of Labor Statistics**. 2021. National Occupational Employment and Wage Estimates. U.S. Department of Labor. https://www.bls.gov/oes/current/oes_nat.htm. Accessed 2 April 2022.

25. **Prasad K, McLoughlin C, Stillman M, Poplau S, Goelz E, Taylor S, Nankivil N, Brown R, Linzer M, Cappelucci K, Barbouche M, Sinsky CA**. 2021. Prevalence and correlates of stress and burnout among U.S. healthcare workers during the COVID-19 pandemic: a national cross-sectional survey study. *EClin Med* **35**:100879.

26. **Brajcich BC, Chung JW, Wood DE, Horvath KD, Tolley PD, Yates EF, Are C, Ellis RJ, Hu YY, Bilimoria KY**. 2021. National evaluation of the association between Resident Labor Union participation and surgical resident well-being. *JAMA Netw Open* **4**:e2123412.

27. **Philbrick IP, Abelson R**. January 30, 2021. Health care unions find a voice in the pandemic, p 1. *The New York Times*, New York, NY.

28. **Committee of Interns and Residents**. 2022. A supermajority of resident physicians at UVM demand union recognition amid staffing shortages, extreme physician burnout. https://www.cirseiu.org/a-supermajority-of-resident-physicians-at-uvm-demand-union-recognition-amid-staffing-shortages-extreme-physician-burnout-2/. Accessed 6 October 2023.

29. **Office of Public Affairs**. 2021. NLRB Invites Briefs Regarding Appropriate Bargaining Units. National Labor Relations Board. https://www.nlrb.gov/news-outreach/news-story/nlrb-invites-briefs-regarding-appropriate-bargaining-units. Accessed 19 October 2023.

30. **Synder JR, Larson AL**. 1983. *Administration and Supervision in Laboratory Medicine*, p 262–280. Harper & Row, Philadelphia, PA.

31. **National Labor Relations Board**. 2023. The Right to Strike. https://www.nlrb.gov/strikes. Accessed 22 August 2022.

32. **Kallas J, Ritchie K, Friedman E**. 2022. Labor action tracker, 2022. ILR School, Cornell University, Ithaca, NY. https://www.ilr.cornell.edu/faculty-and-research/labor-action-tracker-2022. Accessed 6 October 2023.

33. **U.S. Bureau of Labor Statistics**. 2022. *Major Work Stoppages in 2021*, USDL-22-0316. U.S. Department of Labor.

34. **Fitzgibbon RJ**. 1981. *Legal Guidelines for the Clinical Laboratory*, p 280–283. Medical Economics Co, Oradell, NJ.

35. **National Labor Relations Board**. 2022. Election-related content. https://www.nlrb.gov/about-nlrb/rights-we-protect/the-law/election-related-content. Accessed 05 April 2022.

36. 1935. *National Labor Relations Act*. 29 USC §§151-169.

APPENDIX 16.1 Helpful Websites Related to Unions and Collective Bargaining[a]

Federal Mediation and Conciliation Service

www.fmcs.gov/

- Independent agency to promote sound and stable labor-management relations in such areas as dispute mediation, preventive mediation, and alternative dispute resolution. FMCS mediators work from more than 60 field offices around the United States, administered through two regions comprising eight District Offices.

National Labor Relations Board

https://www.nlrb.gov

- Information on the NLRB process, organization chart, cases and decisions, news releases, and more.

United States Department of Labor

https://webapps.dol.gov/elaws/elg/

- Elaws—employment law guide.

American Constitution Society for Law and Policy

https://www.acslaw.org/expertforum/the-future-of-the-national-labor-relations-act/

Communications Workers of America

https://cwa-union.org/national-issues/health-care-retirement-security

Cornell University ILR School Labor Action Tracker

https://striketracker.ilr.cornell.edu/

- Database of strike and labor protest activity across the United States.

U.S. Bureau of Labor Statistics Data Tools

https://www.bls.gov/data/tools.htm

Office of Labor-Management Standards Publications

https://www.dol.gov/agencies/olms/compliance-assistance

[a]All websites accessed 6 October 2023.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 16.2 Do's and Don'ts for Management Regarding Union Activity

Things Management Can Do Regarding Union Activity (34, 35)	Things Management Cannot Do Regarding Union Activity (36)

• Tell employees that if a majority of the employees in the bargaining unit select the union, the employer will have to deal with the union on all their daily problems involving wages, hours, and other conditions of employment. Advise the employees that the employer would prefer to continue working with them directly on such issues
• Emphasize that members of management are always willing to discuss any subject. Remind the employees how earlier problems have been resolved through such discussions
• Remind employees of the benefits they currently enjoy, all of which have been obtained without union representation; avoid threats or promises, either direct or indirect
• Point out how wages, benefits, and working conditions compare favorably with other institutions in the area, whether unionized or not; all information must be factual
• Advise employees of the disadvantages of belonging to a union, such as initiation fees, dues, fines, strike assessments, and membership rules. Quote from the union's constitution and bylaws granting it authority to impose punishment and discipline against its members and giving the international organization power over the local
• Tell employees there is a possibility that a union will call a strike or work stoppage even though many workers may not want one and the employer is willing to negotiate or has already been bargaining
• Point out that any strike can cost employees in lost wages
• Explain that in negotiating with the union, the employer does not have to agree to all of its terms, and certainly not to those terms that are not in the economic interest of the institution
• Relate any experience with unions, especially the ones involving the organizing campaign; be factual
• Provide employees with information about the union or its officers; identify the source of the information
• Point out any untrue or misleading statements made by an organizer, in a pamphlet, or through any other medium; management may always give employees the facts
• Advise employees that signing an authorization card does not mean they have to vote for the union
• Inform employees of the NLRB election procedures and the importance of voting, and emphasize that the vote is by secret ballot
• Make and enforce rules limiting solicitation of membership or discussion of union affairs to outside working time. However, remember that employees can solicit members and discuss the union on their own time, even on the premises, when it does not interrupt work
• Prohibit the distribution of union literature in patient care areas
• Restrict the wearing of union buttons to areas where there is no patient contact
• Enforce all other institution rules impartially in accordance with established procedures
	• Promise employees a pay increase, promotion, benefit, or special favor if they vote against the union
	• Threaten loss of job, reduction of income, or elimination of privileges or benefits
	• Discharge, discipline, or lay off an employee because of union activities (or threaten to do so)
	• Spy on union meetings or create the impression you are spying on employees' union activities
	• Photograph or videotape employees engaged in peaceful union or other protected activities
	• Discriminate against workers actively supporting the union
	• Transfer employees because of union affiliation
	• Show partiality to employees not involved in union activities over those active in union activities
	• Discipline or penalize employees supporting a union for an action permitted to employees not supporting a union
	• Separate pro-union employees from other employees through assignments or transfers
	• Ask employees how they intend to vote in a union election
	• Question workers about whether they belong to a union or have signed an authorization card
	• Inquire about internal affairs of the union
	• Ask employees about the union sentiments of their coworkers
	• Say that the employer will not deal with the union
	• Urge employees to persuade others to oppose the union
	• Give financial support or assistance to a union, its representatives, or employees; this restriction prevents an employer from favoring one union over another
	• Make speeches to assemblies of employees on institution time within the 24-hour period prior to a representative election
	• Call employees to your office or visit their homes to discuss the union
	• Remember these TIPS; do not do the following:
	  • **T**hreaten
	  • **I**ntimidate
	  • **P**romise
	  • **S**py

本书版权归John Wiley & Sons Inc.所有

17

Introduction
Regulated and Nonregulated Testing
Whom To Test
Preemployment Testing • For-Cause or Reasonable Suspicion • Random Testing • Posttreatment Testing
Urine Drug Testing Protocol
Specimen Collection • Specimen Testing • Specimen Validity • Urine Drug Screening • Urine Drug Confirmation • Reporting Results
Alternative Specimen Types
Managing Clinical and Forensic Drug Testing
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENTS
REFERENCES
APPENDIX

Workplace Drug Testing and the Clinical Laboratory

Lindsay A. L. Bazydlo

OBJECTIVES

To learn the rationale for and differences between regulated and nonregulated testing

To provide guidelines for collection, testing, and reporting of results in workplace drug testing

To give the reader insight into the commonalities and differences between clinical and forensic drug testing

Doveryai, no proveryai. (Trust but verify.)

Russian proverb

On December 8, 1987, President Ronald Reagan quoted this Russian proverb as the opening statement to the signing of the Medium Range Missile Treaty with the Soviet Union. The English translation, "Trust but verify," could just as well have been stated the previous year, when on September 15, 1986, President Reagan signed Executive Order 12564, Drug-Free Federal Workplace, launching the first widespread initiative to deter drug use in the workplace. One can reasonably argue that this maxim of trust and verify is a core principle for this new federal workplace drug testing program. Twenty-five years later, regulated (federal) and nonregulated (private sector) drug testing is commonplace in our culture. Clinical laboratory scientists (CLSs), whether they manage a federal laboratory or a private sector laboratory, may utilize their expertise and understanding of quality management to enhance the hiring process for their own employees as well as the institution they represent. While the human resources (HR) department sets the guidelines for the hiring process, the CLS manager can represent a vital quality and technical resource for the employer's drug policy. After all, drug testing results are laboratory results, and who recognizes the need for quality laboratory results better than the CLS manager?

Technical competence and quality assurance are the foundation of any laboratory. This is also true for any workplace drug testing program. Reviewing processes for workplace drug testing provides CLS managers an opportunity to understand how basic laboratory management skills can benefit their employers' drug testing policies. The hiring of qualified laboratory staff and maintenance of a safe working environment for the laboratory are direct benefits of a well-designed workplace drug testing policy.

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch17.

本书版权归John Wiley & Sons Inc.所有

Regulated and Nonregulated Testing

The Mandatory Guidelines for Workplace Drug Testing Programs clearly define federal workplace drug testing as to the drugs/drug class and specimen validity parameters to be tested (1), as shown in Table 17.1. The majority of laboratories are in the state or private employment sector and must be considered for nonregulated testing. While some states may have specific requirements for workplace drug testing of laboratory employees, private sector laboratories are free to design their own programs. Certainly, these documents have been used as a reference point for nonregulated testing. Many private sector employers choose to broaden the scope and depth of the requirements. This may include changing the cutoff concentration for each analyte screened (higher or lower) as well as increasing the number of drugs and drug classes tested from five to 10 or more. A key difference is the creatinine requirement, with many nonregulated protocols raising the cutoff of acceptability to 20 mg/dl (2). This is an effective change to detect and deter the donor from diluting a drug with mass quantities of water prior to submitting a sample. Another important aspect is the need for confirmation of any presumptive (preliminary) positive screening result. *Trust but verify*.

Whom To Test

Workplace drug testing is designed to provide a safe work environment, discourage drug use, and provide assistance in the treatment, recovery, and return to work of individuals with substance abuse problems. As stated by The Council on Alcohol and Drugs (3), "The one place where there can be mandated adult education is the workplace." Testing acts not only as a deterrent, but also as an opportunity to educate about the problems of substance abuse.

The most common utilization of workplace drug testing includes (4):

- *Preemployment testing as a condition of hiring*. Testing of applicants may be restricted to a particular job description or category, such as safety-sensitive positions, or may be applied as a nondiscriminatory practice to all applicants for all positions.
- *For-cause or reasonable suspicion*. Performed when coworkers or supervisors observe inappropriate behavior, work performance, or behavior indicative of drug impairment/intoxication. Specific and detailed policies for identifying worker impairment and subsequent testing should be followed with this testing, to avoid claims of discrimination, personal vendetta, or the like.
- *Post-accident testing*. As outlined by the employer's HR policy, testing may be a routine requirement to protect the employer and the employee in worker's compensation claims stemming from on-the-job injury.
- *Random testing*. Selection for testing is performed using an unpredictable process and is the most effective for deterring illicit drug use.
- *Posttreatment testing*. Performed when employees return to work after completing a rehabilitation program.

Table 17.1 Analytes and cutoff concentrations for federally regulated testing[a]

Initial test analyte	Initial test cutoff concn (ng/ml)	Confirmatory test analyte	Confirmatory test cutoff concn (ng/ml)
Marijuana metabolites	50	THCA[b]	15
Cocaine metabolites	150	Benzoylecgonine	100
Codeine/morphine[c]	2,000	Codeine	2,000
		Morphine	2,000
6-Acetylmorphine	10	6-Acetylmorphine	10
Phencyclidine	25	Phencyclidine	25
Amphetamine/methamphetamine[d]	500	Amphetamine	250
		Methamphetamine[e]	250
MDMA[f]/MDA[g]	500	MDMA	250
		MDA	250
Hydrocodone/hydromorphone	300	Hydrocodone	100
		Hydromorphone	100
Oxycodone/oxymorphone	100	Oxycodone	100
		Oxymorphone	100

[a] Effective date: October 1, 2017 (1).
[b] THCA, delta-9-tetrahydrocannabinol-9-carboxylic acid.
[c] Morphine is the target analyte for codeine/morphine testing.
[d] Either a single initial test kit or multiple initial test kits may be used, provided the single test kit detects each target analyte independently at the specified cutoff.
[e] To be reported as positive for methamphetamine, a specimen must also contain amphetamine at a concentration greater than or equal to 250 ng/ml.
[f] MDMA, methylenedioxymethamphetamine.
[g] MDA, methylenedioxyamphetamine.

本书版权归John Wiley & Sons Inc.所有

Preemployment Testing

With this approach, all job candidates will receive drug testing prior to being hired. At some point in the hiring process, the job candidate will be required to submit a specimen for testing. This should come as no surprise to the candidate, as it is routine on many applications to make the candidate aware that this employer requires completion and passing of a urine drug test in order to be hired. The goal of this practice is to ensure that the candidate chosen during the hiring process will not be a safety issue to coworkers or to the patients served through the quality of results generated by the laboratory.

For-Cause or Reasonable Suspicion

For-cause drug testing should follow a written policy and procedure that document the preliminary steps taken prior to collection and analysis. This policy should be approved by the employer's risk management or legal department. The request should document a specific administrative approval chain of command. Rationale for conducting a for-cause test must be based on specific, objective, and articulated facts. Any drug history related to the source of impairment is beneficial to establishing the breadth of the testing to be performed. Much has been reported about identifying and treating addicted healthcare workers (5). Specific statistics on clinical laboratory employees have not been reported.

Random Testing

Preemployment testing notification before and during the hiring process forewarns an applicant with recreational or chronic substance abuse issues to take steps to avoid detection. Random testing is an effective and continuous monitoring tool available for maintaining a drug-free workplace (6). The element of surprise in random testing allows no time to attempt to take adulterants or delay testing. Notification of intent to test and a defined time to complete collection are critical to the success of random testing. There should be strict guidelines in a written policy prior to implementing testing (6). Checking state and federal guidelines for allowance of random testing is advisable. All employees must have an equal chance of being tested to eliminate any hint of bias or discrimination.

Posttreatment Testing

A worker seeking help with a substance abuse problem is required to submit to monitoring (testing) during and upon completion of the recovery program (6). The benefits to the employer and manager are as significant as those to the employee. The time, effort, and expense to recruit, hire, and train new personnel are greater than the cost of the employee assistance program and the cost of drug testing during the monitoring for return to duty.

Urine Drug Testing Protocol

Specimen Collection

A vulnerable point of the drug testing process is at specimen collection. In nonregulated testing, direct observation is generally not an option. A review of the collection procedure is beneficial to ensure that the process is sound. The fundamentals should include a clear and concise chain of custody, a control form, a controlled physical environment at the collection site, and a well-trained collector.

Figure 17.1 shows the first page of a federal drug testing custody and control form (7).

- Copy 1 is retained by the testing laboratory.
- Copy 2 is completed by the medical review officer (MRO).
- Copy 3 is identical to copy 2 and is the collector's copy.
- Copy 4 is identical to copy 2 and is given to the employer.
- Copy 5 is identical to copy 2 and is given to the donor.

The back of copy 5 contains the specimen collection instructions (Fig. 17.2).

A criterion for specimen collection is outlined in Subpart H of the Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA) *Collection Site Manual* (see Appendix 17.1). The *Collection Site Manual* is an excellent standard to follow when training collectors and implementing an effective urine collection process. Accurately documenting the process is critical to protecting the integrity of the donor, the collector, and the results. Experience in understanding the necessity to link the requisition, specimen, and result is second nature in CLS management and is a valuable insight to the forensic collection process and requirements. It is the chain of custody that distinguishes the clinical from the medicolegal. Although clinical laboratories may experience mislabeled, misplaced, or lost specimens (albeit a relatively small percentage for the volume of specimens received and processed), forensic documentation is specifically designed to negate any such occurrence. The chain-of-custody/control form, initiated at collection, represents a diary of that specimen through the preanalytical, analytical, and postanalytical processes. Furthermore, each aliquot's disposition associated with the process can be traced from the original sample bottle (1, 6, 8).

Specimen Testing

After collection, the initial step in testing is receipt of the sample, while verifying and maintaining the chain of custody. The difference in managing the clinical receiving process from a forensic receiving requirement is not the verification of sample demographics but the documentation of that verification (8). Any evidence of tampering,

本书版权归John Wiley & Sons Inc.所有

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

SPECIMEN ID NO. 0000001

STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE ACCESSION NO.

A. Employer Name, Address, I.D. No. B. MRO Name, Address, Phone No. and Fax No.

C. Donor SSN or Employee I.D. No. _____

D. Specify Testing Authority: ☐ HHS ☐ NRC ☐ DOT – Specify DOT Agency: ☐ FMCSA ☐ FAA ☐ FRA ☐ FTA ☐ PHMSA ☐ USCG

E. Reason for Test: ☐ Pre-employment ☐ Random ☐ Reasonable Suspicion/Cause ☐ Post Accident ☐ Return to Duty ☐ Follow-up ☐ Other (specify) _____

F. Drug Tests to be Performed: ☐ THC, COC, PCP, OPI, AMP ☐ THC & COC Only ☐ Other (specify) _____

G. Collection Site Address:

Collector Phone No. _____

Collector Fax No. _____

STEP 2: COMPLETED BY COLLECTOR (make remarks when appropriate) Collector reads specimen temperature within 4 minutes.

Temperature between 90° and 100° F? ☐ Yes ☐ No, Enter Remark | Collection: ☐ Split ☐ Single ☐ None Provided, Enter Remark | ☐ Observed, Enter Remark

REMARKS

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)

STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY TEST FACILITY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service noted in accordance with applicable Federal requirements.

X _____ Signature of Collector

(PRINT) Collector's Name (First, MI, Last) | Date (Mo/Day/Yr) | Time of Collection AM PM

SPECIMEN BOTTLE(S) RELEASED TO: Name of Delivery Service

RECEIVED AT LAB OR IITF:

X _____ Signature of Accessioner

(PRINT) Accessioner's Name (First, MI, Last) | Date (Mo/Day/Yr)

Primary Specimen Bottle Seal Intact ☐ YES ☐ NO If NO, Enter remark in Step 5A.

SPECIMEN BOTTLE(S) RELEASED TO:

STEP 5A: PRIMARY SPECIMEN REPORT - COMPLETED BY TEST FACILITY

☐ **NEGATIVE** ☐ DILUTE ☐ **POSITIVE** for: ☐ Marijuana Metabolite (Δ9-THCA) ☐ Cocaine Metabolite (BZE) ☐ PCP ☐ 6-Acetylmorphine ☐ Morphine ☐ Codeine ☐ Methamphetamine ☐ Amphetamine ☐ MDMA ☐ MDA ☐ MDEA

☐ **REJECTED FOR TESTING** ☐ **ADULTERATED** ☐ **SUBSTITUTED** ☐ **INVALID RESULT**

REMARKS: _____

Test Facility (if different from above) : _____

I certify that the specimen identified on this form was examined upon receipt, handled using chain of custody procedures, analyzed, and reported in accordance with applicable Federal requirements.

X _____ Signature of Certifying Technician/Scientist | (PRINT) Certifying Technician/Scientist's Name (First, MI, Last) | Date (Mo/Day/Yr)

STEP 5b: COMPLETED BY SPLIT TESTING LABORATORY

Laboratory Name

Laboratory Address

☐ **RECONFIRMED** ☐ **FAILED TO RECONFIRM** - REASON _____

I certify that the split specimen identified on this form was examined upon receipt, handled using chain of custody procedures, analyzed, and reported in accordance with applicable Federal requirements.

X _____ Signature of Certifying Scientist | (PRINT) Certifying Scientist's Name (First, MI, Last) | Date (Mo./Day/Yr.)

0000001 SPECIMEN ID NO. A | PLACE OVER CAP | 0000001 SPECIMEN BOTTLE SEAL | Date (Mo/Day/Yr) | Donor's Initials

0000001 SPECIMEN ID NO. B (SPLIT) | PLACE OVER CAP | 0000001 SPECIMEN BOTTLE SEAL | Date (Mo/Day/Yr) | Donor's Initials

OMB No. 0930-0158

PRESS HARD - YOU ARE MAKING MULTIPLE COPIES

Version C 14May2010

COPY 1 - TEST FACILITY COPY

Figure 17.1 The first page of the federal drug testing custody and control form (7). There are multiple copies of this form to serve as documentation for donor, collector, laboratory, and medical review officer.

本书版权归John Wiley & Sons Inc.所有

BACK COPY 5

Instructions for Completing the Federal Drug Testing Custody and Control Form

When making entries use black or blue ink pen and press firmly

Collector ensures that the name and address of the HHS-certified Instrumented Initial Test Facility (IITF) or HHS-certified laboratory are on the top of the CCF and that the Specimen I.D. number on the top of the CCF matches the Specimen I.D. number on the labels/seals.

STEP 1:

- Collector ensures that the required information is in STEP 1. Collector enters a remark in STEP 2 if Donor refuses to provide his/her SSN or Employee I.D. number.
- Collector gives collection container to Donor and instructs Donor to provide a specimen. Collector notes any unusual behavior or appearance of Donor in the remarks line in STEP 2. If Donor conduct at any time during the collection process clearly indicates an attempt to tamper with the specimen, Collector notes the conduct in the remarks line in STEP 2 and takes action as required.

STEP 2:

- Collector checks specimen temperature within 4 minutes after receiving the specimen from Donor, and marks the appropriate temperature box in STEP 2. If temperature is outside the acceptable range, Collector enters a remark in STEP 2 and takes action as required.
- Collector inspects the specimen and notes any unusual findings in the remarks line in STEP 2 and takes action as required. Any specimen with unusual physical characteristics (e.g. unusual color, presence of foreign objects or material, unusual odor) cannot be sent to an IITF and must be sent to an HHS-certified laboratory for testing as required.
- Collector determines the volume of specimen in the collection container. If the volume is acceptable, Collector proceeds with the collection. If the volume is less than required by the Federal Agency, Collector takes action as required, and enters remarks in STEP 2. If no specimen is collected by the end of the collection process, Collector checks the *None Provided* box, enters a remark in STEP 2, discards Copy 1 and distributes remaining copies as required.
- Collector checks the Split or Single specimen collection box. If the collection is observed, Collector checks the Observed box and enters a remark in STEP 2.

STEP 3:

- Donor watches Collector pour the specimen from the collection container into the specimen bottle(s), place the cap(s) on the specimen bottle(s), and affix the label(s)/seal(s) on the specimen bottle(s).
- Collector dates the specimen bottle label(s)/seal(s) after placement on the specimen bottle(s).
- Donor initials the specimen bottle label(s)/seal(s) after placement on the specimen bottle(s).
- Collector turns to Copy 2 (Medical Review Officer Copy) and instructs Donor to read and complete the certification statement in STEP 5 (signature, printed name, date, phone numbers, and date of birth). If Donor refuses to sign the certification statement, Collector enters a remark in STEP 2 on Copy 1.

STEP 4:

- Collector completes STEP 4 on Copy 1 (signature, printed name, date, time of collection, and name of delivery service), places the sealed specimen bottle(s) and Copy 1 of the CCF in a leak-proof plastic bag, seals the bag, prepares the specimen package for shipment, and distributes the remaining CCF copies as required.

Privacy Act Statement: (For Federal Employees Only)

Submission of the information on the attached form is voluntary. However, incomplete submission of the information, refusal to provide a urine specimen, or substitution or adulteration of a specimen may result in delay or denial of your application for employment/appointment or may result in removal from the Federal service or other disciplinary action.

The authority for obtaining the urine specimen and identifying information contained herein is Executive Order 12564 ("Drug-Free Federal Workplace"), 5 U.S.C. Sec. 3301 (2), 5 U.S.C. Sec. 7301, and Section 503 of Public Law 100-71, 5 U.S.C. Sec. 7301 note. Under provisions of Executive Order 12564 and 5 U.S.C. 7301, test results may only be disclosed to agency officials on a need-to-know basis. This may include the agency Medical Review Officer (MRO), the administrator of the Employee Assistance Program, and a supervisor with authority to take adverse personnel action. This information may also be disclosed to a court where necessary to defend against a challenge to an adverse personnel action.

Submission of your SSN is not required by law and is voluntary. Your refusal to furnish your number will not result in the denial of any right, benefit, or privilege provided by law. Your SSN is solicited, pursuant to Executive Order 9397, for purposes of associating information in agency files relating to you and for purposes of identifying the specimen provided for testing. If you refuse to indicate your SSN, a substitute number or other identifier will be assigned, as required, to process the specimen.

Public Burden Statement:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0158. Public reporting burden for this collection of information is estimated to average: 5 minutes/donor; 4 minutes/collector; 3 minutes/test facility; and 3 minutes/Medical Review Officer. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer, 1 Choke Cherry Road, Room 7-1044, Rockville, Maryland, 20857.

Figure 17.2 Instructions for completing the federal drug testing custody and control form, found on the back page of the form shown in Fig. 17.1.

本书版权归John Wiley & Sons Inc.所有

errors, or irregularities is strictly noted and is a potential fatal error to continuing the process toward analysis. All scenarios should be detailed in the policy and procedures. Once verified, accepted, and logged into the laboratory, aliquots can be prepared from the original sample(s) to perform analytical testing.

Specimen Validity

Collected urine samples are subjected to testing for specimen validity, to ensure the sample collected is actually urine and is suitable for drug testing. This testing is performed as a panel which includes pH, creatinine, and a test for identifying the presence of oxidants. Based on the results of the specimen validity testing, urines could reported as adulterated, dilute, substituted, or invalid. An "adulterated" specimen is identified as a urine with the presence of an exogenous substance, usually identified by the oxidants testing or by having a pH outside the normal range of 4–11. A "dilute" urine is identified by having a creatinine of <20 mg/dl, which would trigger a reflex specific gravity measurement. As long as the creatinine is >5 mg/dl and specific gravity is >1.0010, but less than 1.0030, then the sample is reported as dilute along with the drug testing results. A urine is reported as "substituted" if the creatinine result is <2 mg/dl and the specific gravity falls outside of the range of 1.0010–1.0200, indicating that it may not be urine. "Invalid" as a result can refer to a number of different scenarios, including but not limited to an abnormal physical characteristic, an unidentified adulterant, the presence of an inhibitor, or an endogenous analyte present at a concentration not compatible with human urine. In this case, the sample may not be urine or could have something present that would interfere with the ability of the laboratory to complete the drug testing (2).

Urine Drug Screening

Immunoassay is the most common analytical method (8) to perform the initial screening for drugs of abuse. A CLS manager may be acquainted with one or more immunoassay techniques. Available methodologies for screening may include enzyme immunoassay, fluorescence polarization immunoassay, and particle assays. Batch analysis provides economy of scale and cost efficiency. An important distinction in forensic drug testing is that quality control samples are included with each batch of samples, at a greater frequency than necessary in clinical testing. A typical forensic sample batch consists of positive, negative, and blank (1, 8) samples. The positive control will contain the specific analytes to be tested, typically at a concentration 20 to 25% *above* the cutoff calibration concentration. The negative control will contain the specific analytes to be tested at a concentration 20 to 25% *below* (1, 8) the cutoff calibration concentration. The blank control is a *true drug-free* (1, 8) sample. The utility of the negative control in the forensic batch, followed by the blank control, is an effective safeguard for the presence of carryover by the instrument. Additional positive and negative controls are placed within the batch, with a recommended frequency of one set per 10 samples. The blank is only analyzed once.

Urine Drug Confirmation

In nonregulated testing, an employer may have specific concerns or rationale for requesting cutoff concentrations that differ from the standards specified by the Department of Health and Human Services for regulated testing. Direction and guidance may be required to assist the employer (or the laboratory's own HR department) in selecting the correct calibration or specific immunoassay to best meet the expressed desire. Most importantly, the chosen method and cutoff for screening provide only a "presumption" of the presence of drug or drug metabolite and therefore must be confirmed by an alternative methodology.

Once a specimen within the screening batch has been identified as "presumptive positive" for a particular drug or metabolite, confirmation must be performed on a new aliquot from the original sample (9). It is essential that all presumptive positive results be confirmed by an *alternative* method, using a calibration cutoff *at least as sensitive as* the screening cutoff (8). The accepted standard for confirmation is mass spectroscopy (MS), with either gas chromatography (GC) or liquid chromatography (LC) as the separation technique (9). Recent technology advances have allowed for more sophisticated choices to include a tandem mass spectrometer (MS-MS) coupled to either a GC or LC instrument. With MS technology, the cutoff concentration for confirmation can be tied to specific drugs and metabolites at greater sensitivity and lower concentration than with immunoassay. Use of GC-MS and/or LC-MS-MS technology for drug confirmation or clinical testing has the added management challenges of hiring, training, and retaining personnel with the skills and proficiency necessary to provide accurate, reliable, and defendable results.

Reporting Results

Workplace drug testing results require specific review. Designated, experienced, and qualified personnel certify both negative and presumptive positive screened results (9). Presumptive positive screens subjected to confirmation testing are certified as confirmed positive or negative. Certified positive results in regulated testing are

本书版权归John Wiley & Sons Inc.所有

required to undergo final review by a certified medical review officer (MRO) (6). Indeed, the use of an MRO review for nonregulated testing is a valuable and beneficial quality assurance procedure. The MRO is responsible for making the final determination about the validity of the confirmed positive result. The donor may have legitimate reasons for testing positive for a particular drug or metabolite in the urine sample provided for testing. Through personal contact and interview, the MRO may determine if the positive result is caused by a valid medication or from medical treatment (6). Therefore, a confirmed positive by the laboratory may have a final negative result reported by the MRO, with the employer or client unaware of the presumptive positive or confirmed positive result. The MRO's training and certification provide the combined medical and analytical expertise (6) to make the correct final analysis of the result.

Alternative Specimen Types

Oral fluid has been approved as an alternative specimen choice. The requirements state that the collection should be performed supervised and that two specimens be collected from the donor. A minimum volume of 1 ml must be collected. Oral fluid will be subjected to the same two-test system as urine, where it undergoes a screening test followed by confirmation of positive results. The cutoff concentrations in oral fluid are different from those for urine and can be found in Table 17.2. Specimen validity testing needs to be available on request by the MRO and could include measuring albumin, IgG, or presence of oxidants, and/or physical assessment of the color, odor, or other properties of the oral fluid.

Managing Clinical and Forensic Drug Testing

While standards and requirements for clinical and workplace drug testing share commonalities (8), the intertwining of clinical and forensic specimens is to be avoided. The instrumentation utilized for analysis of both specimen types may be the same, but it is important to have separate policies and procedures for each. Batching of specimens is cost-effective for any analysis, but clinical specimens must be sequestered from forensic specimens. Following sound chain-of-custody practices will prevent mixing clinical and forensic specimens when the same analyzer must be used for both.

The training, skill, and documentation of competency in workplace drug testing may involve greater detail for the personnel engaged in this activity within the clinical laboratory. As stated previously, the instrumentation and methods of analysis for clinical and workplace drug testing may be identical for a particular laboratory, but the detailed documentation for forensic specimens may seem onerous to the clinical laboratorian. Identifying laboratory personnel to perform specific functions and maintain specific responsibilities for workplace drug testing is key to management.

Table 17.2 Analytes and cutoff concentrations for oral fluid (10)[a]

Initial test analyte	Initial test cutoff concn (ng/ml)	Confirmatory test analyte	Confirmatory test cutoff concn (ng/ml)
Marijuana (THC)	4	THC	2
Cocaine/benzoylecgonine	15	Cocaine	8
		Benzoylecgonine	8
Codeine/morphine	30	Codeine	15
		Morphine	15
6-Acetylmorphine	4	6-Acetylmorphine	2
Phencyclidine	10	Phencyclidine	10
Amphetamine/methamphetamine	50	Amphetamine	25
		Methamphetamine	25
MDMA/MDA	50	MDMA	25
		MDA	25
Hydrocodone/hydromorphone	30	Hydrocodone	15
		Hydromorphone	15
Oxycodone/oxymorphone	30	Oxycodone	15
		Oxymorphone	15

[a] Effective date, January 1, 2020. See Table 17.1 for abbreviations.

本书版权归John Wiley & Sons Inc.所有

SUMMARY

Workplace drug testing is a reality of employment in the majority of small and large businesses. Clinical laboratories may choose to expand revenue and service opportunities within this growing market. Expertise in the preanalytical, analytical, and postanalytical procedures for workplace drug testing is an achievable goal for successful workplace drug testing.

KEY POINTS

- The instrumentation and methodology for clinical and workplace drug testing are similar.
- Workplace drug testing involves expertise with accreditation standards, requirements, and implementation.
- Management policies for drug testing benefit from technical knowledge provided by the laboratory. Whether contributing as the site of testing or not, the CLS management should be actively engaged in providing technical and practical expertise to ensure a safe workplace for their laboratory.
- Drug and drug classes to be tested differ for regulated (federal) and nonregulated workplace drug testing. Accreditation is required for regulated testing (SAMHSA). Nonregulated testing may be subject to state law and require either SAMHSA or College of American Pathologists Forensic Drug Testing accreditation.
- A medical review officer (MRO) is required for regulated testing and may be a state requirement for nonregulated testing. Review by a certified MRO is strongly recommended for nonregulated workplace drug testing programs.

GLOSSARY

American Association of Medical Review Officers (AAMRO) Voluntary medical organization dedicated to establishing national standards for the certification of medical practitioners who perform drug and alcohol testing.

College of American Pathologists Forensic Drug Testing (CAP-FDT) Accreditation for forensic drug testing by the College of American Pathologists provides standards and proficiency in forensic drug testing. Drugs and drug classes included in the proficiency go beyond the limited scope designated in mandatory federal drug testing programs.

Cutoff concentration The concentration of drug designated to determine a positive screening or confirmatory test from a negative result.

Enzyme immunoassay A competitive binding assay that employs an enzyme-bound antibody to detect a specific antigen (drug). The enzyme catalyzes a reaction when exposed to a substrate, and the reaction rate is measured spectrophotometrically to quantitate the concentration of antigen.

Fluorescence polarization immunoassay Fluoroimmunoassay in which detection of the hapten-antibody reaction is based on measurement of the increased polarization of a fluorescence-labeled hapten when it is combined with antibody. The assay is very useful for the measurement of small haptenic antigens such as drugs at low concentrations.

Gas chromatography–mass spectrometry (GC-MS) Analytical instrument that consists of two methodologies. The gas chromatography portion separates the sample into a pure compound, and the mass spectrometer identifies and quantifies the compound based on structure.

Kinetic microparticle immunoassay Immunoassay in which a conjugate reagent consists of drug bound to microparticles. The microparticle conjugates in solution minimally block light transmission. When antibody to the drug is added to the conjugate solution, lattice formation takes place as the antibodies cross-link the microparticles by binding to the drug moieties. The resulting lattice structure effectively blocks light transmission and increases absorbance. Unconjugated drug in the sample competes with the drug conjugates for antibody-binding sites, and the degree of lattice formation is inhibited proportional to the concentration of the drug in the urine.

Liquid chromatography–mass spectrometry (LC-MS-MS) Analytical technique that combines the physical separation capabilities of liquid chromatography with the mass analysis capabilities of dual mass spectrometers.

Medical review officer (MRO) The role of the medical review officer is to review and interpret lab results obtained through a forensic drug testing program. The MRO must be a licensed physician trained and certified in the knowledge of substance abuse, interpretation of analytical results for drugs of abuse, and evaluation of medical history and relevant biomedical information to render a final decision on positive drug results.

Substance Abuse and Mental Health Services Administration (SAMHSA) Branch of U.S. Department of Health and Human Services charged with improving the quality and availability of prevention, treatment, and rehabilitative services to reduce illness, death, disability, and cost to society resulting from substance abuse and mental health. The administrator of SAMHSA reports directly to the secretary of the U.S. Department of Health and Human Services. The agency is responsible for accreditation of all laboratories engaging in federal workplace drug testing.

ACKNOWLEDGMENTS

I would like to acknowledge the contributions of Jimmy R. Lea, author of this chapter in the 2nd edition of *Clinical Laboratory Management*.

本书版权归John Wiley & Sons Inc.所有

REFERENCES

1. **Federal Register**. 2019. Substance Abuse and Mental Health Services Administration: mandatory guidelines for federal workplace drug testing programs. *Fed Regist* **82**(13):7920.

2. **Department of Health and Human Services, SAMHSA**. 2020. *Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs*. https://www.samhsa.gov/sites/default/files/2020-mro-manual.pdf. Accessed 24 July 2023.

3. **The Council on Alcohol and Drugs**. 2021. Drug free workplace FAQ. https://www.livedrugfree.org/drug-free-workplace/drug-free-workplace-faq/. Accessed 10 February 2023.

4. **U.S. Department of Health and Human Services, SAMHSA**. 2023. Drug testing resources. https://www.samhsa.gov/workplace/drug-testing-resources. Accessed 8 March 2023.

5. **Kenna GA, Lewis DC**. 2008. Risk factors for alcohol and other drug use by healthcare professionals. *Subst Abuse Treat Prev Policy* **3**:3.

6. **Shults TF**. 2009. *Medical Review Officer Handbook*, 9th ed. Quadrangle Research, LLC, Research Triangle Park, NC.

7. **U.S. Department of Health and Human Services, SAMHSA**. 2017. Federal drug testing custody and control form. https://www.samhsa.gov/sites/default/files/workplace/2017-federal-ccf.pdf. Accessed 10 February 2023.

8. **Clinical and Laboratory Standards Institute**. 2017. Toxicology and drug testing in the clinical laboratory. Approved guideline. 3rd ed. CLSI document C52. Clinical and Laboratory Standards Institute, Wayne, PA.

9. **Jenkins AJ**. 2020. Forensic drug testing, p 45–63. *In* Levine BS, Kerrigan S (ed), *Principles in Forensic Toxicology*. Springer Nature Switzerland AG, Basel, Switzerland.

10. **Federal Register**. 2019. Mandatory Guidelines for Federal Workplace Drug Testing Programs – Oral/Fluid. *Fed Regist* **84**(207):57554.

APPENDIX 17.1 Websites

COLLECTION SITE MANUAL

https://www.samhsa.gov/sites/default/files/workplace/collection-site-manual-oct2017_2.pdf (accessed 10 February 2023)

AMERICAN PRESIDENCY PROJECT

https://www.presidency.ucsb.edu/documents/executive-order-12564-drug-free-federal-workplace (accessed 10 February 2023)

This section presents Ronald Reagan's Executive Order 12564—Drug-Free Federal Workplace.

THE COUNCIL ON ALCOHOL AND DRUGS

https://www.livedrugfree.org/drug-free-workplace/drug-free-workplace-faq/ (accessed 10 February 2023)

Drug-Free Workplace FAQ.

FEDERAL REGISTER

https://federalregister.gov (accessed 10 February 2023)

A department of the National Archives, this government agency archives all government directives and documents. Information on current and past revisions to federal regulations may be accessed by the public.

NATIONAL ARCHIVES, OFFICE OF THE FEDERAL REGISTER

http://www.archives.gov/federal-register/codification/executive-order/12564.html (accessed 10 February 2023)

The formal citation for Executive Order 12564—Drug-Free Federal Workplace.

本书版权归John Wiley & Sons Inc.所有

IV

Requirements for Effective Laboratory Management

(SECTION EDITOR: **Andrea J. Linscott**)

18 Quality Management
Lynne S. Garcia

19 International Organization for Standardization
Anne Marsden and Amy Shahtout

20 Effective Communication in Laboratory Management
Andrea Linscott and Elise Occhipinti

21 Laboratory Information Systems
Melinda L. Doherty and Kenneth E. Youens

22 Management of Point-of-Care Testing
Laura Smy, Kristine Apfeld, Sarah Ampomah, and Molly Thieme

23 Principles of Preanalytic and Postanalytic Test Management
Lynne S. Garcia and Andrea J. Linscott

24 Selection and Implementation of New Equipment and Procedures
Paula Revell and Lakshmi Chandramohan

25 Laboratory Safety
Cameron A. Brown and James J. Dunn

26 Emergency Management
Andrea J. Linscott and Natalie Williams-Bouyer

本书版权归John Wiley & Sons Inc.所有

本书版权归John Wiley & Sons Inc.所有

18

Quality Management

Lynne S. Garcia

Introduction

Quality Management of Preanalytical Processes

Test Selection and Ordering • Quality of Specimen Collection • Patient and Client Satisfaction • Specimen Transport, Storage, and Receipt and Preanalytical Processing

Quality Management of Analytical Processes

Method Selection and Evaluation • Quality Control • Quality Control Rules • Frequency of Quality Control Analysis • Specification of MAE • Use of Patient Data for Quality Control • External Quality Control (Proficiency Testing)

Quality Management of Postanalytical Processes

Turnaround Time

Corrected and Incomplete Reports

Document Control

SUMMARY

KEY POINTS

GLOSSARY

ACKNOWLEDGMENTS

REFERENCES

APPENDIXES

OBJECTIVES

To understand the three phases of the total testing process

To understand factors affecting quality of test ordering, specimen collection, and patient satisfaction

To understand basic statistical processes involved in monitoring analytical performance

To understand factors affecting test turnaround time

To understand the role of corrected and incomplete reports in quality management

To understand systems for document control

Quality has to be caused, not controlled.

PHILIP CROSBY, *REFLECTIONS ON QUALITY*

QUALITY MANAGEMENT IS A SYSTEM for continuously analyzing, improving, and reexamining resources, processes, and services within an organization (1–6). This is accomplished by defining quality indicators that are measured and either analyzed over time or compared to similar or identical indicators from other departments or organizations (benchmarking) (7). The primary objective of quality management is to achieve the best possible outcome. Quality indicators provide information on which to base strategies for improvement, and quality is achieved by reducing variability by standardizing these processes across the organization. Managing the development and implementation of a quality program requires a global understanding of the various resources, processes, and outcomes associated with laboratory medicine as well as healthcare systems and their regulatory environment in general. Laboratory quality includes accurate, reliable, and prompt reporting of test results. The laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely to be useful for patient care in all healthcare settings (8).

The design of a quality management system depends in large part on expected outcomes. For example, processes involving identification of patient specimens for blood transfusion purposes are much more rigorous than those for identifying patient specimens for general chemistry testing; the possible risk of a poor outcome from a misidentified specimen is substantially higher

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch18.

本书版权归John Wiley & Sons Inc.所有

for the blood bank example. Fortunately, poor outcomes from laboratory errors are uncommon (9).

Developing an effective quality management program is challenging because the goal of the program (good outcomes) is often difficult to quantify and may involve processes that are not directly under the laboratory manager's control. In this context, quality assessment of laboratory medicine should be viewed as part of the organization's total quality plan. The "total testing process" is a concept that provides a comprehensive working model for evaluating the components of the laboratory's quality management plan as an interdependent component of the organization's total quality improvement program (10–12).

The three phases of the total testing process can be targeted individually for improving quality; however, it is well established that most errors occur in the pre- and postanalytical phases (Table 18.1). The first phase, the preanalytical phase, involves the various processes and resources that precede the testing step. This phase includes proper ordering and test selection by the clinician, patient preparation, specimen collection, identification, transport and/or storage, and premeasurement laboratory processing.

The second phase, the analytical phase, involves managing the reliability of instruments and reagents used for measuring patient specimens and obtaining test results. This phase relies heavily on statistical quality control processes to reduce errors and variation in test measurements. Quality management of the analytical phase is the most standardized and regulated and has therefore received the most attention. The fewest errors occur during this part of the testing cycle. For example, various studies have shown that only 13 to 32% of laboratory errors are due to analytical problems (13). Howanitz et al. (14) have suggested that the heavy focus on laboratory quality control processes has diverted attention and resources away from other equally important quality objectives associated with the pre- and postanalytical phases of testing.

Table 18.1 Types and rates of error in the three stages of the laboratory testing process (10, 11)

Stage	Error	Error rate (%)
Preanalytical	Incorrect/inappropriate test request	46–68.2
	Order entry errors	
	Misidentification of patient	
	Inappropriate container	
	Inadequate specimen collection and/or transport	
	Inadequate specimen/anticoagulant volume ratio	
	Insufficient specimen volume	
	Errors in specimen sorting and/or routing	
	Errors related to specimen labeling	
Analytical	Equipment malfunction	7–13
	Specimen mix-ups/interference	
	Undetected failure in quality control	
	Procedure not followed	
Postanalytical	Failure or inappropriate reporting	18.5–47
	Erroneous validation of analytical data	
	Improper data entry	

The last phase, the postanalytical phase, involves reporting, interpretation, and clinical use of test results. Application of different quality management processes may involve one or a combination of all three phases. For example, turnaround time and examination of reasons for corrected reports are important quality indicators that may cross over any or all phases of the testing process.

The College of American Pathologists (CAP) (http://www.cap.org; accessed 30 April 2023) provides numerous management tools to assist laboratories with quality improvement. Q-Probes and Q-Tracks programs focus on pre- and postanalytical phases of the testing process (7, 15). Several standardized monitors are provided each year to participants. The Q-Probes program provides a series of cross-sectional quality assurance studies with peer evaluations, while the Q-Tracks program provides continuous quality monitors for tracking changes over time. These programs have substantial value for benchmarking performance and tracking improvement. A broad range of Q-Probes studies is available from the CAP for use by laboratories. These predesigned quality assurance studies are linked with historical data for benchmarking performance and can be a useful supplement to a laboratory's quality program.

Organizational structure, personnel information, and utilization management as well as laboratory safety are important components of the total quality management plan and are discussed in other chapters. In addition, many of the laboratory's quality management procedures conducted in clinical laboratories today have been mandated by regulatory and accreditation requirements. Participating in on-site laboratory inspections and appropriate external proficiency programs is required to comply with government regulations.

Quality Management of Preanalytical Processes

The preanalytical phase of the total laboratory testing process is where most laboratory errors occur. Preanalytical errors can be associated with patient assessment, test order entry, request completion, patient identification, specimen collection, specimen transport, or specimen receipt in the laboratory. A report by Bonini and colleagues found that preanalytical errors predominated in the laboratory, with rates ranging from 31.6% to 75% (13).

本书版权归John Wiley & Sons Inc.所有

Test Selection and Ordering

The first step in the testing process involves test selection. Most laboratory testing is ordered by physicians and nurse clinicians; however, other groups, including pharmacists in some jurisdictions, can order tests. Multiple clinical guidelines provide expert opinions about clinical indications for testing based on specific signs, symptoms, or suspected disorders, as well as the literature (16–18). However, guideline implementation has been variable (19). Some approaches for managing the quality of test selection include monitoring the frequency of testing by algorithms and instituting test restriction policies. Limits can be established for test ordering frequency. Thus, for a slowly changing analyte like hemoglobin A1c (used to monitor glucose control in diabetics), some healthcare systems cancel any new test order if the hemoglobin A1c test is ordered within 28 days of the last test (20). Some laboratory information systems can notify the clinician about potential excess ordering patterns when the number of tests (e.g., two serum cholesterol orders within a week) exceeds a predetermined number (21). Use of algorithms in which indications for ordering a test depend on the results of another test or other patient parameters can be effective. Examples include deferring serological testing for acute hepatitis A when alanine aminotransaminase is normal or deferring ova-and-parasite examinations in patients who have been hospitalized for more than 3 days (22). To promote optimal test usage, a multifaceted approach is recommended, including clinician education about laboratory testing, controls on ordering, and feedback about the individual clinician's test utilization.

Some common sources of preanalytical error include transcription errors, ordering tests on the wrong patient, ordering the wrong test, misidentifying the patient, choosing the inappropriate collection container, or labeling containers improperly. Preanalytical errors associated with ordering tests include inaccuracies or omissions when transcribing from paper requisitions into a laboratory computer system, tests performed but not actually ordered, associating the order with the wrong physician, and mistakes related to assigning priority status to the order (e.g., STAT or routine). Of all tests ordered, about 2% are not completed because of these problems (23). In one study involving 660 laboratories, 4.8% of about 115,000 outpatient orders resulted in mistakes (24). The most common was assignment of the wrong physician with an order, and the least common was test priority assignment. High test volume, verbal orders, and lack of laboratory policies and procedures to ensure a high-quality order entry process were associated with higher error rates.

While ordering errors and inappropriate test requests should be tracked and trends should be investigated, major advances in improving the quality of test selection will depend on advances in healthcare information systems strengthening their ability to assist clinicians based on other information in the patient's electronic record (5, 25). Use of computerized test ordering directly by the physician reduces clerical and transcription errors associated with paper requisitions, reduces costs, and improves utilization (26). Electronic access to patients' imaging and laboratory results is not a panacea; physicians who were able to access their patients' radiology and laboratory results online tended to order more tests, especially radiologic tests (27). Modern robotics and information systems can help reduce preanalytical errors. Computerized order entry simplifies test ordering and eliminates the need for a second person to transcribe the orders. Automated phlebotomy tray preparation provides a complete set of labeled blood tubes and labels for hand labeling in a single tray for each patient. Preanalytical robotic workstations reduce the number of steps leading to potential preanalytical errors. Bar codes also simplify specimen routing and tracking (28).

Quality of Specimen Collection

Laboratory test results may be affected by the patient's condition at the time of specimen collection, as well as by the materials and procedures used for specimen collection (29). These types of errors may be overlooked and lead to inaccurate test interpretations or incomplete testing due to specimen rejection (e.g., hemolysis), insufficient volume, or incorrect collection containers. In one study that examined more than 800,000 outpatient visits at 210 facilities, about 0.4% of phlebotomy procedures were unsuccessful (30). The most common causes in order of frequency were nonfasting patient, missing orders, unsuccessful phlebotomy procedure, patient leaving the collection area, and patient not being prepared for test (other than nonfasting status). Of the successful blood collections, 0.26% of specimens were unsuitable for testing. In order of decreasing frequency, this was caused by hemolyzed specimen, insufficient specimen volume, clotting of anticoagulated specimen, lost specimen, mislabeling, and rejection based on delta check failure. Other studies have shown that about 0.35% of specimens submitted for chemistry examinations are rejected, with hemolysis being the most common reason, and about 0.45% of specimens received for hematology testing are rejected, with specimen clotting being the most common reason (31, 32). The quality of coagulation testing depends on good collection technique, full sampling, and complete mixing (33, 34).

Well-documented and validated specimen collection procedures used by trained phlebotomy and nursing staff are key factors to prevent preanalytical errors from affecting the overall quality of the testing process. It is important to provide patients with detailed instructions about preparation prior to specimen collection and then to make sure the instructions were followed. For example, two

本书版权归John Wiley & Sons Inc.所有

consecutive studies have found that between 25 and 34% of toxic serum digoxin levels were likely falsely elevated due to specimen collection too soon after patients ingested their medication (35). These falsely high results can be avoided by instructing phlebotomists to ask patients when they last took a digoxin pill to determine if specimen collection should be deferred to a later time. To mitigate the problem of falsely elevated digoxin results in northern Alberta, an interdisciplinary team of a clinical biochemist, pharmacists, and clinicians mandated evening digoxin dosing. This nocturnal dosing coupled with the usual morning therapeutic monitoring has resulted in very few incorrectly timed digoxins (D. LeGatt, personal communication). Phlebotomists should always ask if a patient is fasting prior to collecting a specimen for triglyceride, as false elevation of serum triglyceride occurs in specimens collected from nonfasting patients, making this determination meaningless. Measuring total creatinine on 24-h urine specimens helps determine whether a complete 24-h collection was obtained, and this can be monitored as a quality indicator. These examples emphasize the importance of having comprehensive guidelines required for each test request.

Microbiology specimens that are not collected correctly will produce useless or even misleading results that may be detrimental to patient care. Specimen quality can be evaluated by smear examinations before cultures are performed, and these specimens may be rejected if judged unacceptable. Excessive epithelial cells seen on a Gram stain from a sputum specimen suggest that the specimen contents are from the mouth rather than the lower respiratory tract; this may warrant rejection of the specimen for culture. While contaminated cultures from sterile sources cannot be eliminated, they can be reduced with good aseptic collection techniques. Proper sterile preparation of the venipuncture site with the correct materials and careful collection procedures by a properly trained phlebotomist significantly reduce the cost of blood culture contamination, which varies up to 5-fold between laboratories (36, 37). Blood collection processes have important implications for costs and outcomes. In one comprehensive literature review, overall blood culture contamination rates ranged from 0.9% to 41%. Up to 59% of patients received unnecessary treatment with parenteral vancomycin, resulting in increased pharmacy charges between $210 and $12,611 per patient. Increases in total laboratory charges between $2,397 and $11,152 per patient were reported. Attributable increases in hospital length of stay due to blood culture contamination ranged from 1 to 22 days (38). Finally, the specimen may be collected properly, but there may be insufficient blood volume or inadequate specimen numbers to provide the highest-quality result. For example, collection of solitary rather than multiple blood cultures makes it difficult to differentiate contamination from true bacteremia when coagulase-negative *Staphylococcus* sp. is isolated (39). As another example, the failure to collect enough sputum specimens is the most common cause of delayed diagnosis of tuberculosis in HIV-infected patients (40).

It is critical that specimens be labeled correctly. The frequency of and reasons for incorrect patient identification should be part of the laboratory's quality assessment program. Delta checking (see "Use of Patient Data for Quality Control") is a method in which the laboratory manager establishes parameters in the laboratory information system that flag current patient results that differ substantially from previous results (41, 42). Generally, delta checks are not very helpful in highly automated laboratories because of the relative absence of sample mix-up and analytic error. Delta checks also lack utility for most analytes because of large, expected changes in these analytes (e.g., glucose). Other analytes are more sensitive (e.g., red blood cell mean corpuscular volume). Depending on how the parameters are set, only a small proportion of delta check investigations will uncover specimen mix-up errors in today's healthcare organizations, where the median identification error rate is 4 per 10,000 references (43–45).

Environmental conditions also play a role in determining specimen acceptability. Specimens collected off-site are typically stored at the site and transported to the clinical laboratory via courier. Geographic location, season, method of storage, and method of transport can impact overall specimen quality, which can lead to inaccurate test results. Specimens collected on site may also be subjected to suboptimal storage and transport environments. Specimens delivered via a pneumatic tube system can experience extreme shaking and rapid accelerations and decelerations. Suboptimal storage and transport temperatures are less likely to occur within healthcare systems due to regulatory requirements for temperature monitoring; however, temperature checks may not be consistent throughout the preanalytical phase. Strategies to alleviate environmentally induced preanalytical errors and regulatory gaps for environmental monitoring in the preanalytical phase are important to consider (46).

Patient and Client Satisfaction

Often, the only direct experience patients have with the laboratory is during phlebotomy. Patient satisfaction with this experience is an important preanalytical quality measurement. This is determined by patient surveys as well as objective parameters, such as patient waiting times or number of self-reported hematomas (47), number of needlesticks, and even the cleanliness of the phlebotomy area.

Laboratories should also conduct nurse and physician satisfaction surveys. Excessively long turnaround time is usually the most significant concern expressed by both physicians and nurses (32). Esoteric test turnaround time

本书版权归John Wiley & Sons Inc.所有

has been associated with low levels of physician satisfaction (48). Nurse customers were the least satisfied with test turnaround time in the intensive care units and emergency departments (49). Setting up a hotline through which clients can report potential problems or errors and make inquiries may help large laboratories improve customer support services. It is useful to track this information to look for trends or ideas for quality improvement.

Specimen Transport, Storage, and Receipt and Preanalytical Processing

It is difficult to monitor collection and transport times when the collection is not under the control of the laboratory. Specimens that are lost or mishandled in other ways (e.g., broken tubes) during transport or preanalytical laboratory processing should be tracked as a quality indicator (see "Corrected and Incomplete Reports"). Specifications for specimen transport and storage based on stability of analytes should be validated and documented.

Accurate identification of the specimen throughout the testing process is facilitated using bar codes that can be scanned by laboratory instruments prior to testing (50). Bar codes are significantly more reliable than the manual entry of specimen information. Bar-coded specimens prevent errors due to misplacement of specimens into instruments or when aliquoting specimens into secondary containers. Bar code systems work best when integrated into the blood collection process with wristband (inpatient) or identification card (outpatient) positive patient identification schemes. Finally, significant error reduction can be accomplished with the implementation of robotic technology for the automated handling of all aspects of preanalytical within-laboratory specimen processing (51, 52).

Quality Management of Analytical Processes

The analytical phase begins when the patient specimen is prepared in the laboratory for testing, and it ends when the test result is interpreted and verified by appropriate laboratory personnel. Improper processing can affect test results in the analytical phase. Establishing and verifying test method performance specifications (accuracy, precision, sensitivity, specificity, and linearity) are other areas where errors can occur in the analytical phase of laboratory testing. Quality management of the analytical phase involves reducing inaccuracy and imprecision (variability) of test methods as much as possible (11). Attention to standardizing test procedures and monitoring method performance with a well-designed quality control system are the key elements for meeting this management goal. Appropriate method selection and proper training are additional factors that are important for success.

Method Selection and Evaluation

Method selection varies among laboratories and is based on characteristics that best fit individual laboratory internal goals for cost, timeliness, and reliability. These characteristics include specimen type required, sample volume, run size, population to be tested, instrument capacity, analysis time, personnel requirements, existing equipment, safety, utilities (e.g., electrical and water), and space requirements. The complexity of analysis, including calibration, stability of reagents and controls, sensitivity and specificity of the method, linear range of analysis, and interferences, as well as types of internal and external proficiency systems, are factors that may affect method selection decisions. In the United States, most laboratory methods require review of rigorous premarket evaluations and approval by the Food and Drug Administration (FDA). As a result, implementation of FDA-approved tests is usually relatively straightforward. Validation and implementation of non-FDA-approved methods can be much more complex and labor-intensive and require substantially more development and evaluation, as well as resources. Sometimes, the best decision is to outsource a test when rapid turnaround time is not necessary, test volume is low, or it is difficult to maintain an acceptable quality of proficiency.

Method evaluation and implementation involve assessing the analytical process statistically using control materials, establishing and validating the reference (normal) range of the population being tested, documenting the procedure in writing (one document for laboratory use and another for client use), and training personnel (Table 18.2). When a new method is introduced, it must be compared to the old method before it is brought into use. All procedure changes, training, and analytical performance data from

Table 18.2 Method evaluation and implementation

Stage	Step
I	Prepare and document procedure
	Validate linearity and calibration
	Determine within-run imprecision
	Evaluate for interferences
II	Determine between-day imprecision
	Compare to old method
	Evaluate acceptability of imprecision and bias
	Perform or validate reference range(s)
III	Establish final quality control ranges, critical values, and delta checks
	Train personnel
	Complete and sign procedure documents
	Notify clients of any significant changes in method

本书版权归John Wiley & Sons Inc.所有

the previous method should be documented, and clients should be notified of changes affecting interpretation of results.

Quality Control

The term "quality control" describes the approach used to monitor the analytical process to ensure that the test results meet their quality requirements. Quality control includes establishing specifications for the analytical process, monitoring the analytical process to determine conformance to these specifications, and taking any necessary corrective actions to bring the analytical process into conformance.

The primary quality characteristic that is monitored during the analytical process is the deviation of an analytical measurement from expected. If the deviation (also known as error) is outside the accepted limits, the analytical process may be defective and requires investigation. Errors can be classified as systematic (resulting in a shift) or random (resulting in increased imprecision). They may also be classified as persistent or intermittent. Other typically monitored quality characteristics of the analytical process include specific equipment checks that are usually unique to each instrument.

The deviation of the analytical result is usually monitored by repetitively assaying one or more levels of quality control specimens. The results of testing these commercially prepared, stabilized control specimens are compared to a range of expected values. If the quality control result deviates significantly, routine patient specimen analysis is suspended, the analytical run is investigated, and corrective action is taken.

Usually, two or three different control levels are used. In hematology and hormone (ligand) measurements, it is standard to use three levels; in general chemistry, two levels are standard. As a rule, it is better to have more measurements on fewer control products. Laboratories may also compare their own quality control results to those generated in other laboratories using the same lot of control materials and instrument/reagent systems. This information may be obtained from most commercial manufacturers of quality control materials and provides a way to assess bias and imprecision of the laboratory's methods relative to others' tests performed under similar quality control conditions. Quality control systems for microbiological and serological testing are primarily qualitative. Control testing is performed to check the performance of media, biochemical reactions (positive or negative), immunological reactions, or expected growth in the presence of antibiotics (susceptibility testing). In molecular microbiology, more than three standards are typically used to generate standard curves for quantitative measurements and are combined with two or three density levels (e.g., low density, mid-density, and high density), external positive controls, or standards.

Quality Control Rules

Quality control rules developed for the clinical laboratory originated in the early 1950s with Levey-Jennings charts. These charts were implemented with three standard deviation (SD) limits for the mean and range of two controls analyzed just twice per week. By the 1960s, the limits had been reduced to two SD for single controls. In the next decade, statistical quality control rules were implemented to help reduce the number of false rejections. Table 18.3 shows some of the common quality control rules used to evaluate control measurements today. Westgard et al. have developed a nomenclature for these control rules and devised graphical summaries (power function curves) of their sensitivity and specificity (53, 54). For most applications of clinical laboratory quality control, a combination of the 1-3SD and the 2-2SD control rules is adequate. Variations of these rules have been adapted for testing platforms in quantitative molecular microbiology (55).

Frequency of Quality Control Analysis

The more frequently control products are analyzed, the more quickly analytical errors can be detected, investigated, and corrected. For some tests, government regulations specify the longest period over which controls need not be analyzed. While many laboratories analyze controls more frequently, the government-mandated period tends to become a *de facto* standard for control analysis. The average time to detect a persistent error has been shown to be one-half of the period between control analyses (56). Thus, if the period between control analyses is 24 h, an error may impair laboratory testing for an average of 12 h before being detected. It is possible to shorten the interval between control analyses without increasing the number of controls analyzed. Rather than analyzing several controls one after another, each control can be tested at different times of the day. As a result, the period between instances of control testing is shortened. For example, rather than analyze three blood gas controls every 24 h, one can be tested every 8 h. Using this control analysis schedule, the average time to detect a persistent error will be 4 h.

In some laboratories, the number of controls analyzed depends on the number of patient specimens run. Because reference laboratories can analyze large numbers of specimens over the course of a day, regular but infrequent control analysis may result in large numbers of samples being analyzed with minimal information provided about the run quality. As such, many reference laboratories test their patient samples in batches, with a specific number of controls analyzed in each batch. Only when the quality control specimens are within quality control limits is the batch of patient results reported.

本书版权归John Wiley & Sons Inc.所有

Table 18.3 Common quality control rules

Rule	Description	Comments
1-2SD	Use as a rejection or warning when one control observation exceeds the x – (±2SD) control limits; usually used as a warning.	Overused. Should be used only with manual assays with low numbers of analytes/control materials.
1-3SD	Reject a run when one control observation exceeds the x – (±3SD) control limits.	Detects random error and large systematic error.
1-3.5SD	Reject a run when one control observation exceeds the x – (±3.5SD) control limits.	Detects large random and systematic error. Use only with highly precise assays.
1-4SD	Reject a run when one control observation exceeds the x – (±4SD) control limits.	Detects large random and systematic error. Use only with highly precise assays.
2-2SD	Reject a run when two consecutive control observations are on the same side of the mean and exceed the x – (+2SD) or x – (−2SD) control limits.	Detects systematic error.
4-1SD	Reject a run when four consecutive control observations are on the same side of the mean and exceed either the x – (+1SD) or x – (−1SD) control limits.	Detects small systematic error; very few applications.
10_x	Reject a run when 10 consecutive control observations are on the same side of the mean.	Detects very small errors; do not use.
R-4SD	Reject a run if the range or difference between the maximum and minimum control observation out of the last 4 to 6 control observations exceeds 4SD.	Detects random errors; use within run.
x-0.01	Reject a run if the mean of the last N control observations exceeds the control limits that give a 1% frequency of false rejection (P_{fr} = 0.01).	Underutilized
R-0.01	Reject a run if the range of the last N control observations exceeds the control limits that give a 1% frequency of false rejection (P_{fr} = 0.01).	Underutilized

Table 18.4 Comparison of maximum allowable errors derived from physiological variation to typical instrument imprecisions

Analyte	MAE (%), 95% limits	Typical imprecision (%)	MAE/imprecision
Serum albumin	3.9	1.5	2.6
Urinary albumin	46.1	8	5.8
Urinary creatinine, 24 h	6.9	2.5	2.8
Activated partial thromboplastin time	4.5	3	1.5
Hemoglobin	4.1	0.8	5.1
Serum sodium	0.9	0.8	1.1
Urinary sodium, 24 h	28.8	4	7.2

Specification of MAE

The primary function of quality control is to maintain a stable analytic process. Once the process is stable, then any required improvements can be implemented. Specifications for maximum allowable error (MAE) provide information about the adequacy of an analytic system for patient care. MAE represents the magnitude of total error that can be tolerated without invalidating the medical relevance of the result. The analytical quality of a test can be evaluated by comparing its total analytic error to the MAE; this is a method for setting goals for the analytical performance of a laboratory test.

Different approaches have been used for determining the MAE of laboratory tests, several based on interindividual variation (ranging from no greater than one-quarter of the analyte's normal reference interval to less than one-half of the intraindividual range).

Table 18.4 compares the MAE for specific analytes to typical amounts of imprecision of current laboratory analyzers. There is tremendous variation in the MAEs, ranging from around 1% for serum sodium to 30% for various urine assays. The MAE/imprecision ratio is a measure of the analytical quality of the test method. The ratio can be thought of as the magnitude of shift, expressed in standard deviations, which will render a test measurement unfit for medical usage. Thus, for sodium, whose ratio is approximately 1, just a 1% shift in measured sodium might make the measurement too inaccurate for serial monitoring.

本书版权归John Wiley & Sons Inc.所有

Table 18.5 Control rules that can be used for various MAE/imprecision ratios[a]

MAE/imprecision	Control rule
2 to 4	Multirule consisting of combination of 1-3SD, 2-2SD, and R-4SD (2 or 3 control levels at start-up)
3.5 to 5	1-2.5SD (2 or 3 control levels at start-up)
4.5 to 7	1-3SD or 1-3.5SD (2 or 3 control levels at start-up)

[a] Adapted with permission from reference 58.

Sodium is an extreme example because its plasma concentration is tightly controlled by multiple feedback mechanisms. Where a test's MAE/imprecision ratio is less than 2.5, it is highly desirable that the manufacturer reduce the method's imprecision. This is a better approach than adding extra quality control samples to attempt to detect small analytical errors on a system that has insufficient reproducibility. For analytes with MAE/imprecision ratios of 2.5 or less, the combination of the 1-3SD and 2-2SD rules, possibly combined with the R-4SD rule, is recommended. Table 18.5 shows recommended quality control rules for various MAE/imprecision ratios. Whenever possible, the laboratory manager should deploy instruments that provide tests with MAE/imprecision ratios that exceed 3.5. For analytical systems with high MAE/imprecision ratios, it is possible to employ control rules with very low false-rejection probabilities, such as 1-3SD, 1-3.5SD, or even 1-4SD (57, 58) (Fig. 18.1).

Unfortunately, selection of analyte-specific control rules can require variations in the timing of quality control testing. Changes in testing frequency are difficult, because many quality control analytes are measured together on a single instrument. It is almost impossible in a busy hospital laboratory to schedule more frequent analyte-specific quality control testing and interpretation. Also, not all instruments can automatically sample and analyze on-board quality control material on a per-analyte basis. As a result, most laboratories use the same schedule of control analysis for all the analytes measured. Some laboratories apply analyte-specific quality control rules using a sophisticated laboratory information system or instrument-based quality control systems.

Use of Patient Data for Quality Control

All laboratories that perform patient specimen testing must alert the caregiver regarding critical results (incompatible with life). Each laboratory must have a critical value list that specifies the limits for alerting the caregiver (59–61). In the past, a test would be repeated if the initial results were "critical." Unfortunately, this retesting approach delays the reporting of the critical value to the caregiver. As improved analyzers become more precise, and because it is often determined that repeat values are substantially the same, laboratories are ending the practice of confirming the critical value. These decisions should be data driven; if an evaluation of the last 50 to 100 critical-value repeats does not yield clinically significant differences, the laboratory director can confidently suspend this increasingly non-value-added practice.

For analytes exhibiting large random errors (usually in the low-volume, manual laboratory), specimens should be analyzed in duplicate with the average reported if the difference between duplicates does not exceed certain limits—generally around ±5%. Some laboratories use duplicate analyses of another type: patient-sample comparisons. These comparisons require the regular analysis of split samples on identical or dissimilar instruments that measure the same analyte. Differences between instruments that exceed predetermined limits are investigated and corrected. Too often, these comparisons are performed retrospectively and contribute little to quality improvement. We recommend that the analyst enter the patient comparison data into an active database; outlying data should be signaled immediately to the analyst and laboratory supervisor. Such prospective analysis can easily be followed by reanalysis of another sample, adjustment of calibration, perhaps widening of the acceptable differences, and rarely, instrument replacement.

The use of the average of patient (AOP) data is another control procedure that uses patient data. In the AOP data approach, an error is signaled when the average of consecutive centrally distributed patient data is beyond the control limits. The assumption underlying the use of AOP data is that the patient population is stable. Any shift would thus be secondary to an analytical shift. The error detection capabilities of the AOP data method depend on several factors (62). Important factors include the number of patient results averaged and the variances of the patient population and analytical method.

The AOP data method has been used extensively in hematology to monitor patient red blood cell indices and, indirectly, their constituent measurements, hemoglobin and red blood cell count, as well as hematocrit (63). The primary limitation of the AOP data approach in the hospital laboratory is the lack of randomization in the order of receipt and analysis of patient samples. In hematology, for example, the averaging of many specimens from a neonatal unit or a hematology unit can cause the red blood cell indices to inappropriately indicate that values are outside the control range. In clinical chemistry, analysis of specimens primarily from renal units will cause large shifts in the AOP of creatinine, glucose, and urea nitrogen. In referral laboratory testing, there is "natural randomization" of patient specimens, and the AOP data method is a powerful tool for guaranteeing acceptable analytical performance (64). The hospital laboratory AOP data are

本书版权归John Wiley & Sons Inc.所有

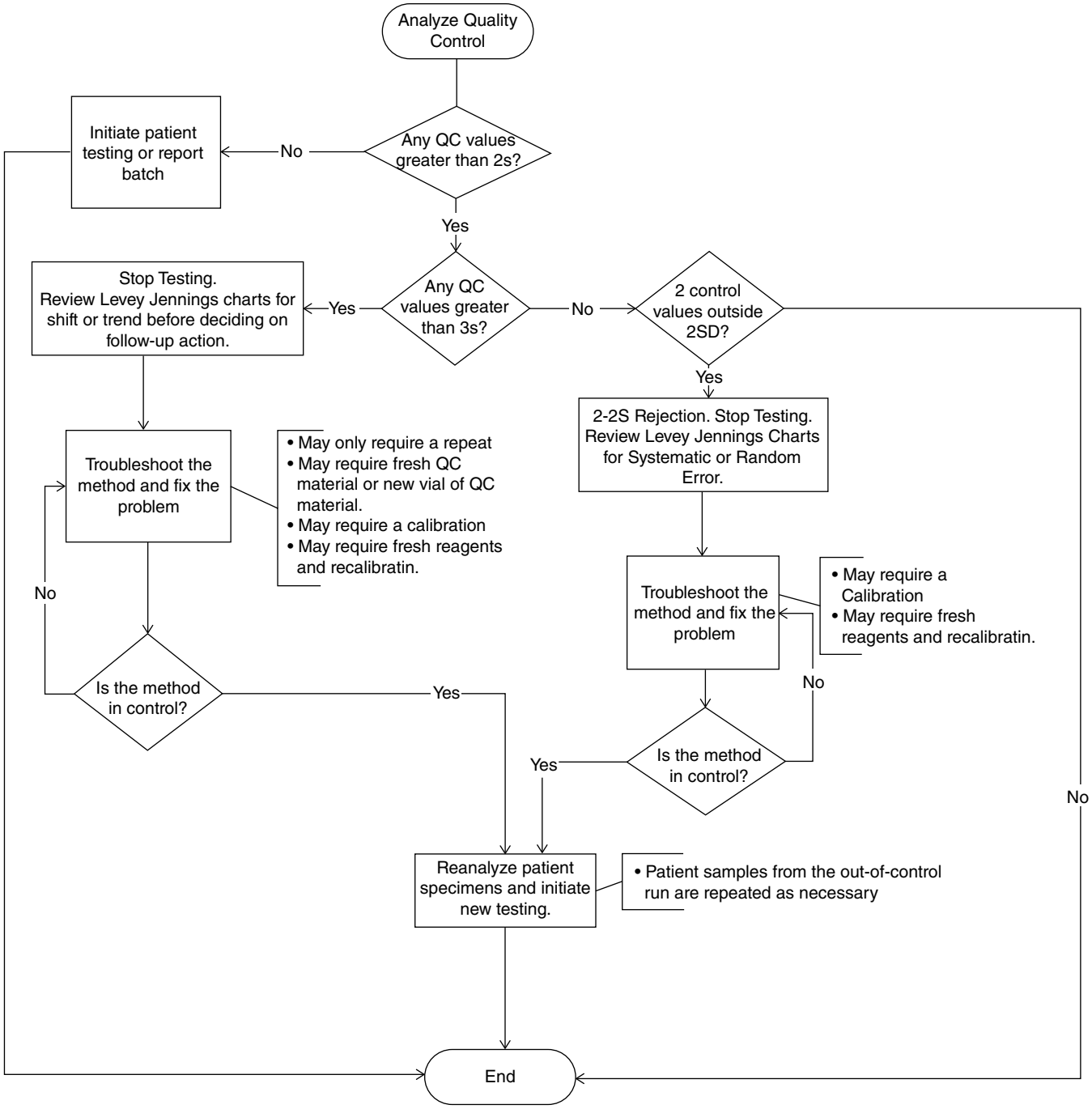


Figure 18.1 Flow chart showing implementation of the 2-2SD/1-3SD control procedure. Courtesy of Tammy Hofer.

significantly influenced by longer-term, within-day and within-week trends. Overnight and over weekends, less testing is ordered; this weekend and nightly testing is performed on more acutely ill patients. As a result, these evening and weekend AOP data will demonstrate elevated glucose, lower sodium, lower protein, and lower calcium averages (65).

One other quality control approach uses patient data: the delta check, in which the most recent result for a patient is compared to the previous value. The difference between consecutive laboratory values (delta) is calculated and compared to previously established limits (42). A difference that exceeds these limits is investigated; this difference is the result of either specimen mix-up or real changes in the patient's test results. The difference is usually calculated in two ways: as a numerical difference (current value minus last value) and as a percentage difference (numerical difference times 100 divided by the current value). There is

本书版权归John Wiley & Sons Inc.所有

a tremendous range in the true positive rate of delta check methods depending on the analyte and its delta limit (41). While delta checks are almost universally applied, the cost of investigating the many false positives is significant, especially in tertiary-care hospital populations in which there are large fluctuations in laboratory values secondary to disease or therapy.

External Quality Control (Proficiency Testing)

Proficiency-testing programs provide samples of unknown concentrations of analytes to participating laboratories. Their purpose is to evaluate the ability of laboratory personnel to achieve the correct answer. Participation in these programs is usually government mandated, with the premise that acceptable performance indicates proficiency in patient specimen analysis. This assumes that proficiency specimens are comparable to and treated the same as patient specimens. Acceptable performance is determined by some form of consensus by peer comparisons using "fixed limits," which are expressed either in measurement units of the analyte (e.g., ±0.5 mmol/liter from the mean for potassium) or as percentages (e.g., ±10% for total cholesterol) or as accurate organism identifications (66). Statistically defined limits of acceptability are used for a number of methods; examples of testing criteria for acceptable external proficiency testing performance (routine chemistry and hematology) can be seen in Table 18.6. Testing criteria for other laboratory disciplines (Microbiology/§§493.911 through 493.919; General Immunology/493.927; Endocrinology/§493.933;

Table 18.6 CLIA testing criteria for acceptable external proficiency testing performance[a]

Test or analyte[b]	Acceptable performance (+ target value)
Routine chemistry (§493.931)	
Alanine aminotransferase	±15% or ±6 U/liter (greater)
Albumin	±8%
Alkaline phosphatase	±20%
Amylase	±20%
Aspartate aminotransferase	±15% or ±6 U/liter (greater)
Bilirubin, total	±20% or ±0.4 mg/dl (greater)
Blood gas pO_2	±15% or ±15 mm Hg (greater)
Blood gas pCO_2	±8% or ±5 mm Hg (greater)
Blood gas pH	±0.04
B-natriuretic peptide	±30%
Pro-B-natriuretic peptide	±30%
Calcium, total	±1.0 mg/dl
Carbon dioxide	±20%
Chloride	±5%
Cholesterol, total	±10%
Cholesterol, high-density lipoprotein	±20% or ±6 mg/dl (greater)
Cholesterol, low-density lipoprotein, direct measurement	±20%
Creatine kinase	±20%
Creatine kinase-MB isoenzymes	±25% or ±3 ng/ml (greater) or MB elevated (presence or absence)
Creatinine	±10% or ±0.2 mg/dl (greater)
Ferritin	±20%
Gamma glutamyl transferase	±15% or ±5 U/liter (greater)
Glucose (excluding measurements devices cleared by FDA for home use.)	±8% or ±6 mg/dl (greater)
Hemoglobin A1c	±8%
Iron, total	±15%
Lactate dehydrogenase	±15%
Magnesium	±15%
Potassium	±0.3 mmol/liter
Prostate specific antigen, total	±20% or ±0.2 ng/ml (greater)
Procainamide (and metabolite)	25%
Sodium	±4 mmol/liter
Total iron binding capacity (direct measurement)	±20%
Total protein	±8%
Triglycerides	±15%
Troponin I	±30% or ±0.9 ng/ml (greater)
Troponin T	±30% or ±0.2 ng/ml (greater)
Urea nitrogen	±9% or ±2 mg/dl (greater)
Uric acid	±10%
Hematology (including routine hematology and coagulation) (§493.941)	
Cell identification	80% or greater consensus on identification
White cell differential	±3SD based on the percentage of different types of white blood cells in the samples
Erythrocyte count	±4%
Hematocrit (excluding spun hematocrit)	±4%
Hemoglobin	±4%
Leukocyte count	±10%
Platelet count	±25%
Fibrinogen	±20%
Partial thromboplastin time	±15%
Prothrombin time (s or INR)[b]	±15%

[a] Reference 67. Amendments 493.2 and 493.801 through 493.959 (amendatory instructions 2 and 5 through 21) are effective 11 July 2024.

[b] If a laboratory reports a prothrombin time in both international normalized ratio (INR) and seconds, the INR should be reported to the proficiency testing provider program.

本书版权归John Wiley & Sons Inc.所有

Toxicology/§493.937; Immunohematology/§493.959) can be seen in reference 67. The standard deviation index (SDI) is used for this purpose and is calculated as the numerical difference between an individual laboratory's results and the mean of all laboratory results, divided by the standard deviation of all laboratory means. For these analytes, the participant result is acceptable if it falls within ±3 SDI of the group mean.

An alternative multirule system has been developed to evaluate proficiency test results (68). The alternative method is simple and can be used by pathologists, doctorate-level scientists, and medical technologists. The most current approach is illustrated in Fig. 18.2. When significant deviations are detected in a set of five survey results (the mean of the five results exceeding +1.5 SDI, or the range of the observations exceeding 4 SDI, or at least one observation exceeding 75% of the total allowable error), the laboratory records, including the internal quality control results, should be reviewed. Mix-ups of proficiency specimens or of proficiency and clinical specimens should be ruled out.

Whenever possible, aliquots of the survey specimens should be frozen and saved. If the survey results differ significantly from those obtained on peer instruments, these aliquots should be reassayed. Results that still deviate significantly after retesting can indicate a long-term bias. If the deviations are variable in magnitude and direction, there may be a problem with imprecision (random error). If repeat analysis yields satisfactory results, the error probably represented a random error or transient bias encountered during the testing period.

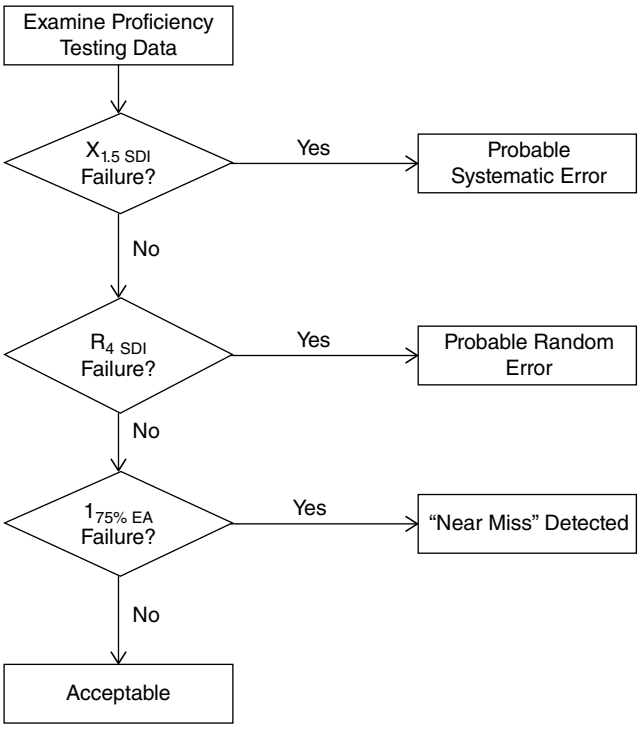


Figure 18.2 Flow chart illustrating proficiency test review, from reference 58 with permission.

Quality Management of Postanalytical Processes

The two most important factors affecting the postanalytical phase of the testing process are test reporting and result interpretation (11, 69, 70). One source of inaccurate reporting is clerical errors due to data entry mistakes. Laboratory instrument interfaces with computer reporting capabilities prevent most of these types of errors. Phone reports have a relatively high rate of errors and should be avoided if possible. It is important to use a minimum of two patient identifiers (patient name and one additional identifier) to minimize possible errors. Also, both The Joint Commission (TJC) and CAP require the healthcare provider to read back the information conveyed during the telephone reporting of patient critical values.

If computer reporting is unavailable, printed results should be promptly delivered to the patient's chart or physician's office. Whenever possible, calculations should be done by preprogrammed computer systems.

Procedures for defining and reporting critical laboratory test results must be developed and periodically reviewed by the laboratory director in conjunction with the medical staff to ensure that clinicians are immediately notified about abnormal results when necessary (71). Common examples of critical values that require immediate notification include severe hypo- or hyperglycemia, thrombocytopenia, and positive blood cultures. Failure to notify a clinician of a critical test result is a serious quality failure and requires investigation.

Turnaround Time

Prolonged laboratory test turnaround time is one of the most common complaints voiced to the laboratory manager (48). The slow delivery of laboratory results is associated with increased diagnostic uncertainty and delays in patient management. From an outcome perspective, long test turnaround times lead to longer waiting times for the patient or incomplete information at the time of a clinical encounter. Pressure to provide test results more rapidly has led, in part, to the growth of point-of-care testing by nonlaboratory personnel outside the main clinical laboratory. Faster service is associated with higher costs and sometimes lower quality of test results. Therefore, it is the laboratory manager's responsibility to determine the most effective testing process and testing schedules that will provide the most cost-effective and reliable results within a clinically appropriate time frame.

Evaluation of test turnaround time is an important component of the laboratory's quality assurance

本书版权归John Wiley & Sons Inc.所有

Table 18.7 Stages in the testing cycle where turnaround time may be measured

Receipt and recording of order
Patient registration
Specimen collection
Specimen delivery
Specimen processing
Testing
Result verification
Result reporting
Interpretation by clinician

program (72). Turnaround time involves all stages of the testing process and is a good way to globally assess performance. Table 18.7 shows the major intervals in the testing process that are potential bottlenecks resulting in delayed testing. Measurement of turnaround time can involve any of these intervals, although the typical measurement is usually specimen collection to result reporting or specimen delivery to result reporting. Typically, the distribution of turnaround times is shifted to the right, with a few cases of prolonged times due to various factors such as verification protocols, dilutions, or instrument malfunction. Therefore, simply taking an average of all turnaround time measurements is misleading. A more appropriate measure is to examine the percentage of outlier turnaround times (73). These are also the events that will most likely be noticed and be of concern to clinicians. The key to this approach is to establish an appropriate target for turnaround time based on the goals of the clinical staff and the capabilities of the laboratory and facilities infrastructure (72).

Corrected and Incomplete Reports

Corrected reports are an important indicator of a failure in one or more laboratory processes. Fortunately, only about 4% of these errors have a significant impact on patient care (74). The most errors tend to be associated with hematology testing, while the fewest are documented in transfusion medicine. Prior to a result being reported, any number of quality processes may come into play to prevent incorrect results from being reported. However, after the result is verified and reported, the defective result has the potential to affect patient outcome. Incorrect results may be detected in a variety of ways, including input from the physician about a clinical inconsistency, a delta check that uncovers a mislabeled sample that was previously tested, delayed recognition of a significant quality control failure, or a clerical error found during routine supervisory review. All corrected reports should be treated as opportunities to reexamine and improve processes to prevent recurrences of the same problem.

Incomplete reporting of results arises from about 2% of orders received by laboratories (23). This may occur for reasons that involve improper specimen collection, an unavailable patient, a broken tube, a lost specimen, misinterpretation of the order, an interfering substance in the specimen, or failure to provide the result in the patient record. Whenever possible, incomplete testing should be reported to the clinician as soon as possible so that testing can be repeated, if necessary. As with corrected reports, incomplete tests should be monitored and examined with the goal of modifying processes to prevent future occurrences.

Document Control

Clinical laboratories process and handle an enormous amount of information each day. These processes require an organized approach for controlling, organizing, and retaining this information and making it readily accessible to busy laboratory staff and laboratory inspectors. Document control can be a challenge to manage; electronic software packages are available to help the laboratory manage its documents. Nationally, the top three laboratory deficiencies identified during CAP on-site inspections in the years 1998 to 2001 were related to document control items (75). TJC inspection of laboratories yields similar results, especially when off-site or multisite laboratories are involved. A document control policy should state the intent and direction the laboratory takes to document and record the structure it uses for creating, revising, approving, distributing, storing, retrieving, and destroying documents. Using the Clinical and Laboratory Standards Institute quality systems approach, documents are broken down into 12 quality system essentials (Table 18.8) to provide laboratories with a mechanism to manage the information required to provide quality laboratory services (1).

SUMMARY

Clinical laboratories are required to have in place a comprehensive quality program. This requires managing the quality of a wide spectrum of resources, procedures, and services by continuously evaluating quality indicators and improving laboratory performance and patient outcomes. The program involves ongoing inspection of the total testing process, from the time a test is ordered until the results are utilized. The quality program is supported by a robust document control system and is conducted by measurement and analysis of indicators to provide information to guide improvement.

本书版权归John Wiley & Sons Inc.所有

Table 18.8 CLSI quality system essentials[a]

Category	Element
Organization	Leadership's commitment to laboratory quality and quality plan
	Organizational charts, definitions, responsibilities, and relationships
Customer focus	Identifies laboratory customers and expectations and a means to monitor
Facilities and safety	Overall safety plan with regard to facility and staff safety and emergency response planning
Personnel	Hiring, training, competency, qualifications, job/position descriptions
Purchasing and inventory	Supplier agreements to provide needed inventory and verification of incoming supplies
Equipment	Selection and installation, equipment list, validation records, operation/maintenance checks
Process management	The path of workflow to make the most efficient use of laboratory resources
Documents and records	Policies, processes, and standard operating procedures that control the creation, revision, approving, distribution, storing, retrieving, and destruction of laboratory documents
Information management	Confidentiality and security of patient information
Nonconforming event management	Reporting and analyzing of events that do not adhere to laboratory policies, processes, or standards
Assessments	Internal and external monitoring to ensure laboratory is meeting requirements
	External proficiency testing, accreditation, and quality indicators
Continual improvement	Identifying opportunities to continually look for ways to improve

[a] See reference 1.

KEY POINTS

- Quality management is a system for continuously analyzing, improving, and reexamining resources, processes, and services within an organization.
- The total testing process provides a comprehensive working model for evaluating the components of the laboratory's quality management plan as an interdependent component of the organization's total quality improvement program.
- Well-documented procedures and trained phlebotomy and nursing staff are key factors for ensuring quality of specimen collection.
- Patient satisfaction is an important quality indicator.
- Quality control is a method for establishing specifications for an analytical process, assessing the procedures, monitoring conformance by statistical analysis, and taking corrective actions to bring the procedures into conformance.
- The two most important factors affecting the postanalytical phase of the testing process are test reporting and result interpretation.
- Turnaround time, corrected reports, and incomplete testing are important indicators for monitoring the total testing process.
- A document control policy should state the intent and direction the laboratory takes to document and record the structure it uses for creating, revising, distributing, storing, retrieving, and destroying documents.

GLOSSARY

Accuracy Agreement between the best estimate of a quantity and its true value.

Analyte Sample to be measured.

Analytical error The difference between the result of an analytical method and the true value.

Analytical method Set of written instructions that describe the procedure, materials, and equipment necessary for the analyst to obtain a result.

Analytical range The range of concentrations or other quantity in the specimen over which the method is applicable without modification.

Bias Systematic error that describes the difference between measured and true or assigned value.

Calibration Process of using standards of known concentration to establish a relationship between the measured signal from the instrument and analyte concentration.

Coefficient of variation A measure of variance expressed as a percentage of the mean ([standard deviation/mean] × 100).

Confidence interval Expected range of values within a group with a specified probability.

Constant systematic error An error that is always in the same direction and of the same magnitude, even as the concentration of analyte changes.

Control limit A range of expected values that, if exceeded, warns of random and/or systematic error in an analytical process.

本书版权归John Wiley & Sons Inc.所有

Control material Specimen that is repeatedly analyzed, with test results statistically analyzed to monitor method performance.

Delta check Rule-based method to compare a patient's current test result to a previous measurement to check for unexpected differences that might be due to analytical or nonanalytical errors in the testing process.

Error Deviation of measured concentration from expected or true value.

Gaussian distribution A random distribution of values described by their average and variance (standard deviation); used to described analytical imprecision.

Imprecision Analytical variance, usually expressed as the standard deviation or coefficient of variation ([standard deviation/mean] × 100).

Interference One or more specimen constituents that cause bias by affecting the analytical method.

Matrix Total constituents of the specimen that may affect the analytical process.

Maximum allowable error (MAE) Amount of error associated with an analytical method that can be tolerated without invalidating the medical usefulness of the result.

Mean Arithmetic average of a set of values.

Medical usefulness limits Quality control limits derived from clinical application of results rather than statistical imprecision of the method.

Normal range See "Reference range."

Proportional systematic error An error that is always in one direction and whose magnitude is a percentage of the concentration of analyte being measured.

Quality assurance A systematic approach to continuously analyzing, improving, and reexamining the total testing process.

Quality control A process for monitoring assay performance to detect deviations from expected outcomes.

Random error A variance from expected that is not reproducible or predictable.

Recovery Amount (usually expressed as percentage) of known quantity of an analyte that is measured when added to a specimen.

Reference range Test results that are within expected parameters for about 95% of all individuals in a defined healthy population. Values outside of the range are classified as abnormal and may be associated with a pathological condition.

Sample Part of specimen that is measured.

Sensitivity, analytical The lowest detection limit of an assay; sometimes measured as the concentration of an analyte that can be differentiated from a blank within a 95% confidence interval.

Specificity, analytical The ability of an analytical method to determine solely the component(s) it purports to measure.

Standard Material of known or assigned concentration used for assay calibration.

Standard deviation A statistic that describes the amount of variance of a set of measurements about the mean value. It is used to describe the random error of an analytical method.

The Joint Commission (TJC) The mission of The Joint Commission is to enable and empower health care organizations around the world to build a foundation for quality care and patient safety.

Turnaround time The interval between the beginning of one event to the end of another event in the total testing process. Typically measured as the time from collection to reporting or from the receipt of specimen in the laboratory to reporting.

Variance Standard deviation squared. Assuming all sources of error are independent of each other, total error is the sum of variances of individual sources of error.

ACKNOWLEDGMENTS

Special thanks go to Ron B. Shifman, George S. Cembrowski, Donna M. Wolk, and Joanne I. Brisbois for their excellent chapter in the second edition of this volume.

REFERENCES

1. **Clinical and Laboratory Standards Institute**. 2011. *Quality Management System: A Model for Laboratory Services; Approved Guideline*, 4th ed. CLSI, Wayne, PA.

2. **Ehrmeyer SS**. 2013. Satisfying regulatory and accreditation requirements for quality control. *Clin Lab Med* **33**:27–40.

3. **Erasmus RT**, **Zemlin AE**. 2009. Clinical audit in the laboratory. *J Clin Pathol* **62**:593–597.

4. **Hawkins R.** 2012. Managing the pre- and post-analytical phases of the total testing process. *Ann Lab Med* **32**:5–16.

5. **Plebani M.** 2010. The detection and prevention of errors in laboratory medicine. *Ann Clin Biochem* **47**:101–110.

6. **Vesper HW**, **Thienpont LM**. 2009. Traceability in laboratory medicine. *Clin Chem* **55**:1067–1075.

7. **Schifman RB**, **Howanitz PJ**, **Zarbo RJ**. 1996. Q-Probes: a College of American Pathologists benchmarking program for quality management in pathology and laboratory medicine. *Adv Pathol* **9**:83–120.

8. **World Health Organization**. 2011. *Laboratory Quality Management System*, version 1.1. WHO Press, Geneva, Switzerland.

9. **Berwick DM**, **Leape LL**. 1999. Reducing errors in medicine. *BMJ* **319**:136–137.

10. **Lippi G**, **Becan-McBride K**, **Behúlová D**, **Bowen RA**, **Church S**, **Delanghe J**, **Grankvist K**, **Kitchen S**, **Nybo M**, **Nauck M**, **Nikolac N**, **Palicka V**, **Plebani M**, **Sandberg S**, **Simundic AM**. 2013. Preanalytical quality improvement: in quality we trust. *Clin Chem Lab Med* **51**:229–241.

11. **Hammerling JA**. 2012. A review of medical errors in laboratory diagnostics and where we are today. *Lab Med* **43**:41–44.

本书版权归John Wiley & Sons Inc.所有

12. Lippi G, Plebani M, Šimundić AM. 2010. Quality in laboratory diagnostics: from theory to practice. *Biochem Med (Zagreb)* **20**:126–130.

13. Bonini P, Plebani M, Ceriotti F, Rubboli F. 2002. Errors in laboratory medicine. *Clin Chem* **48**:691–698.

14. Howanitz PJ, Tetrault GA, Steindel SJ. 1997. Clinical laboratory quality control: a costly process now out of control. *Clin Chim Acta* **260**:163–174.

15. Zarbo RJ, Jones BA, Friedberg RC, Valenstein PN, Renner SW, Schifman RB, Walsh MK, Howanitz PJ. 2002. Q-tracks: a College of American Pathologists program of continuous laboratory monitoring and longitudinal tracking. *Arch Pathol Lab Med* **126**:1036–1044.

16. Connelly DP. 2003. Critical pathways, clinical practice guidelines, test selection and ordering, p 47–63. *In* Ward-Cook KM, Lehmann CA, Schoeff LE, Williams RH (ed), *Clinical Diagnostic Technology. The Total Testing Process, vol. 1. The Preanalytical Phase*. AACC Press, Washington, DC.

17. McQueen MJ. 2001. Overview of evidence-based medicine: challenges for evidence-based laboratory medicine. *Clin Chem* **47**:1536–1546.

18. Murad MH. 2017. Clinical practice guidelines: a primer on development and dissemination. *Mayo Clin Proc* **92**:423–433.

19. Peters M. 1995. Managing test demand by clinicians: computer assisted guidelines. *J Clin Pathol* **48**:98–100.

20. Lyon AW, Higgins T, Wesenberg JC, Tran DV, Cembrowski GS. 2009. Variation in the frequency of hemoglobin A1c (HbA1c) testing: population studies used to assess compliance with clinical practice guidelines and use of HbA1c to screen for diabetes. *J Diabetes Sci Technol* **3**:411–417.

21. Bates DW, Kuperman GJ, Rittenberg E, Teich JM, Fiskio J, Ma'luf N, Onderdonk A, Wybenga D, Winkelman J, Brennan TA, Komaroff AL, Tanasijevic M. 1999. A randomized trial of a computer-based intervention to reduce utilization of redundant laboratory tests. *Am J Med* **106**:144–150.

22. Morris AJ, Murray PR, Reller LB. 1996. Contemporary testing for enteric pathogens: the potential for cost, time, and health care savings. *J Clin Microbiol* **34**:1776–1778.

23. Valenstein PN, Howanitz PJ. 1995. Ordering accuracy. A College of American Pathologists Q-Probes study of 577 institutions. *Arch Pathol Lab Med* **119**:117–122.

24. Valenstein P, Meier F. 1999. Outpatient order accuracy. A College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions. *Arch Pathol Lab Med* **123**:1145–1150 http://dx.doi.org/10.5858/1999-123-1145-OOA.

25. Plebani M, Sciacovelli L, Aita A, Chiozza ML. 2014. Harmonization of pre-analytical quality indicators. *Biochem Med (Zagreb)* **24**:105–113.

26. Delvaux N, Van Thienen K, Heselmans A, Van de Velde S, Ramaekers D, Aergeerts B. 2017. The effects of computerized clinical decision support systems on laboratory test ordering: a systematic review. *Arch Pathol Lab Med* **141**:585–595.

27. McCormick D, Bor DH, Woolhandler S, Himmelstein DU. 2012. Giving office-based physicians electronic access to patients' prior imaging and lab results did not deter ordering of tests. *Health Aff (Millwood)* **31**:488–496.

28. Da Rin G. 2009. Pre-analytical workstations: a tool for reducing laboratory errors. *Clin Chim Acta* **404**:68–74.

29. Miller JJ. 2003. Specimen collection, handling, preparation and storage, p 65–90. *In* Ward-Cook KM, Lehmann CA, Schoeff LE, Williams RH (ed), *Clinical Diagnostic Technology. The Total Testing Process, vol. 1. The Preanalytical Phase*. AACC Press, Washington, DC.

30. Dale JC, Novis DA. 2002. Outpatient phlebotomy success and reasons for specimen rejection. *Arch Pathol Lab Med* **126**:416–419.

31. Jones BA, Calam RR, Howanitz PJ. 1997. Chemistry specimen acceptability: a College of American Pathologists Q-Probes study of 453 laboratories. *Arch Pathol Lab Med* **121**:19–26.

32. Jones BA, Meier F, Howanitz PJ. 1995. Complete blood count specimen acceptability. A College of American Pathologists Q-Probes study of 703 laboratories. *Arch Pathol Lab Med* **119**:203–208.

33. Adcock DM, Kressin DC, Marlar RA. 1998. Minimum specimen volume requirements for routine coagulation testing: dependence on citrate concentration. *Am J Clin Pathol* **109**:595–599.

34. Lawrence JB. 2003. Preanalytical variable in the coagulation laboratory. *Lab Med* **34**:49–57.

35. Howanitz PJ, Steindel SJ. 1993. Digoxin therapeutic drug monitoring practices. A College of American Pathologists Q-Probes study of 666 institutions and 18,679 toxic levels. *Arch Pathol Lab Med* **117**:684–690.

36. Halstead DC, Sautter RL, Snyder JW, Crist AE, Nachamkin I. 2020. Reducing blood culture contamination rates: experiences of four hospital systems. *Infect Dis Ther* **9**:389–401.

37. Doern GV, Carroll KC, Diekema DJ, Garey KW, Rupp ME, Weinstein MP, Sexton DJ. 2019. A comprehensive update on the problem of blood culture contamination and a discussion of methods for addressing the problem. *Clin Microbiol Rev* **33**:e00009–19.

38. Dempsey C, Skoglund E, Muldrew KL, Garey KW. 2019. Economic health care costs of blood culture contamination: a systematic review. *Am J Infect Control* **47**:963–967.

39. Schifman RB, Bachner P, Howanitz PJ. 1996. Blood culture quality improvement: a College of American Pathologists Q-Probes study involving 909 institutions and 289 572 blood culture sets. *Arch Pathol Lab Med* **120**:999–1002.

40. Finch D, Beaty CD. 1997. The utility of a single sputum specimen in the diagnosis of tuberculosis. Comparison between HIV-infected and non-HIV-infected patients. *Chest* **111**:1174–1179.

41. Randell EW, Yenice S. 2019. Delta checks in the clinical laboratory. *Crit Rev Clin Lab Sci* **56**:75–97.

42. Lacher DA. 1990. Relationship between delta checks for selected chemistry tests. *Clin Chem* **36**:2134–2136.

43. Ovens K, Naugler C. 2012. How useful are delta checks in the 21 century? A stochastic-dynamic model of specimen mix-up and detection. *J Pathol Inform* **3**:5.

44. Valenstein PN, Raab SS, Walsh MK, College of American Pathologists. 2006. Identification errors involving clinical laboratories: a College of American Pathologists Q-Probes study of patient

本书版权归John Wiley & Sons Inc.所有

and specimen identification errors at 120 institutions. *Arch Pathol Lab Med* **130**:1106–1113.

45. Strathmann FG, Baird GS, Hoffman NG. 2011. Simulations of delta check rule performance to detect specimen mislabeling using historical laboratory data. *Clin Chim Acta* **412**:1973–1977.

46. Pierre CC, Wiencek JR. 2023. The impact of environmental factors on external and internal specimen transport. *Clin Biochem* **115**:13–21.

47. Howanitz PJ, Cembrowski GS, Bachner P. 1991. Laboratory phlebotomy. College of American Pathologists Q-Probe study of patient satisfaction and complications in 23,783 patients. *Arch Pathol Lab Med* **115**:867–872.

48. Jones BA, Bekeris LG, Nakhleh RE, Walsh MK, Valenstein PN, College of American Pathologists. 2009. Physician satisfaction with clinical laboratory services: a College of American Pathologists Q-probes study of 138 institutions. *Arch Pathol Lab Med* **133**:38–43.

49. Jones BA, Walsh MK, Ruby SG. 2006. Hospital nursing satisfaction with clinical laboratory services: a College of American Pathologists Q-Probes study of 162 institutions. *Arch Pathol Lab Med* **130**:1756–1761.

50. Clinical and Laboratory Standards Institute. 2005. *Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Guideline*, 2nd ed. CLSI, Wayne, PA.

51. Davies N. 2015. Specimen collection automation is on the way. Med Lab Observer. https://www.mlo-online.com/home/article/13008399/specimen-collection-automation-is-on-the-way. Accessed 30 April 2023.

52. Leichtie AB. 2020. Total laboratory automation – samples on track. AACC Clin Lab News. https://www.aacc.org/cln/articles/2020/december/total-laboratory-automation-samples-on-track. Accessed 30 April 2023.

53. Westgard JO, Groth T. 1979. Power functions for statistical control rules. *Clin Chem* **25**:863–869.

54. Westgard JO, Groth T, Aronsson T, Falk H, de **Verdier CH**. 1977. Performance characteristics of rules for internal quality control: probabilities for false rejection and error detection. *Clin Chem* **23**:1857–1867.

55. Liang S-L, Lin M-T, Hafez MJ, Gocke CD, Murphy KM, Sokoll LJ, Eshleman JR. 2008. Application of traditional clinical pathology quality control techniques to molecular pathology. *J Mol Diagn* **10**:142–146.

56. Parvin CA, Gronowski AM. 1997. Effect of analytical run length on quality-control (QC) performance and the QC planning process. *Clin Chem* **43**:2149–2154.

57. Cembrowski GS, Smith B, Tung D. 2010. Rationale for using insensitive quality control rules for today's hematology analyzers. *Int J Lab Hematol* **32**(6p2):606–615.

58. Cembrowski GS. 2012. Hematology quality practices, p 686–706. *In* Kottke-Marchand K, Davis BH (ed), *Laboratory Hematology Practice*. Wiley-Blackwell, Chichester, United Kingdom.

59. Kost GJ. 1990. Critical limits for urgent clinician notification at US medical centers. *JAMA* **263**:704–707.

60. Kost GJ. 1991. Critical limits for emergency clinician notification at United States children's hospitals. *Pediatrics* **88**:597–603.

61. Wagar EA, Friedberg RC, Souers R, Stankovic AK. 2007. Critical values comparison: a College of American Pathologists Q-Probes survey of 163 clinical laboratories. *Arch Pathol Lab Med* **131**:1769–1775.

62. Cembrowski GS. 1986. Use of patient data for quality control. *Clin Lab Med* **6**:715–733.

63. Lunetzky ES, Cembrowski GS. 1987. Performance characteristics of Bull's multirule algorithm for the quality control of multichannel hematology analyzers. *Am J Clin Pathol* **88**:634–638.

64. Cembrowski GS, Parlapiano E, O'Bryan D, Visnapuu L. 2001. Successful use of patient moving averages (PMA) as an accuracy control for multichannel hematology analyzers in a high volume robotic clinical laboratory. *Lab Hematol* **7**:35.

65. Cembrowski GS. 1997. Thoughts on quality-control systems: a laboratorian's perspective. *Clin Chem* **43**:886–892.

66. U.S. Department of Health and Human Services. 1992. Medicare, Medicaid, and CLIA programs. Regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA) final rule. *Fed Regist* **57**:7002.

67. Center for Medicare and Medicaid Services, Center for Clinical Standards and Quality/Quality, Safety & Oversight Group. 2022. Final rule - Clinical Laboratory Improvement Amendments of 1988 (CLIA) proficiency testing - analytes and acceptable performance final rule (CMS – 3355-F. (Ref: QSO-22-21-CLIA). https://www.federalregister.gov/documents/2022/07/11/2022-14513/clinical-laboratory-improvement-amendments-of-1988-clia-proficiency-testing-regulations-related-to#sectno-citation-493.959. Accessed 1 May 2023.

68. Carey RN, Cembrowski GS, Garber CC, Zaki Z. 2005. Performance characteristics of several rules for self-interpretation of proficiency testing data. *Arch Pathol Lab Med* **129**:997–1003.

69. Straseski JA, Strathmann FG. 2013. Patient data algorithms. *Clin Lab Med* **33**:147–160.

70. Walz SE, Darcy TP. 2013. Patient safety & post-analytical error. *Clin Lab Med* **33**:183–194.

71. Piva E, Sciacovelli L, Pelloso M, Plebani M. 2017. Performance specifications of critical results management. *Clin Biochem* **50**:617–621.

72. Howanitz PJ, Cembrowski GS, Steindel SJ, Long TA. 1993. Physician goals and laboratory test turnaround times. A College of American Pathologists Q-Probes study of 2763 clinicians and 722 institutions. *Arch Pathol Lab Med* **117**:22–28.

73. Novis DA, Walsh MK, Dale JC, Howanitz PJ. 2004. Continuous monitoring of stat and routine outlier turnaround times: two College of American Pathologists Q-Tracks monitors in 291 hospitals. *Arch Pathol Lab Med* **128**:621–626.

74. Howanitz PJ, Walker K, Bachner P. 1992. Quantification of errors in laboratory reports. A quality improvement study of the College of American Pathologists' Q-Probes program. *Arch Pathol Lab Med* **116**:694–700.

75. Garcia F, Harrison E, Wise C, Wolk DM. 2003. Is your document control out of control? Complying with document control regulations. *Clin Leadersh Manag Rev* **17**:255–262.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 18.1 Regulations, Guidelines, and Information with Application to a Clinical Laboratory

REGULATIONS GROUPED BY ISSUING AGENCY

FDA

21 CFR 11, Electronic Records; Electronic Signatures, Subpart B—Electronic Records

21 CFR 58, Good Laboratory Practice for Nonclinical Laboratory Studies

58.185 Reporting of nonclinical laboratory study results

58.190 Storage and retrieval of records and data

58.195 Retention of records

21 CFR 211, Current Good Manufacturing Practice for Finished Pharmaceuticals

Subpart J—Records and Reports (211.180–211.198)

21 CFR 600, Biological Products, General

600.12 Records

21 CFR 606, Current Good Manufacturing Practice for Blood and Blood Components

606.100 Standard operating procedures

Subpart I—Records and Reports (606.160–606.171)

21 CFR 640, Additional Standards for Human Blood and Blood Products

640.72 Records

21 CFR 803, Medical Device Reporting of Adverse Events and Certain Malfunctions

803.17–803.18 Written MDR procedures, Files

21 CFR 820, Good Manufacturing Practice, Quality System Regulation

Subpart M—Records (820.180–820.198)

Department of Labor: Occupational Safety and Health Administration (OSHA)

29 CFR 1904, Recording and Reporting Occupational Injuries and Illnesses

1904.6 Retention of records

1904.9 Falsification or failure to keep records or reports

29 CFR 1910 Occupational Safety and Health Standards

Appendix C to 1910.120

4. Training (records)

8. Medical surveillance programs (records)

Department of Health and Human Services: Center for Medicare and Medicaid Services (CMS)

42 CFR 493, Laboratory Requirements (CLIA '88)

493.1107 Test—Records

493.1201(b) Written quality control procedures

493.1202(c)(2) Procedure manual, moderate-complexity testing

493.1211 Procedure manual, high-complexity testing

493.1221 Quality Control—Records

493.1721 Quality Assurance—Records

Department of Health and Human Services, Public Health

42 CFR 72, Interstate Shipment of Etiologic Agents

Department of Transportation

49 CFR 171–7 Shipment of Hazardous Materials

Department of Labor

29 CFR 71—Protection of individual privacy and access to records under the Privacy Act of 1974

MISCELLANEOUS SOURCES

American Clinical Laboratory Association

https://www.acla.com/ (accessed 1 May 2023)

American Medical Technologists

https://americanmedtech.org/ (accessed 1 May 2023)

American Society for Clinical Laboratory Science

https://ascls.org/ (accessed 1 May 2023)

American Society for Clinical Pathology

https://www.ascp.org/content# (accessed 1 May 2023)

American Society for Histocompatibility & Immunogenetics

https://www.ashi-hla.org/default.aspx (accessed 1 May 2023)

American Society of Cytopathology

https://cytopathology.org/ (accessed 1 May 2023)

American Society for Microbiology

https://asm.org/ (accessed 1 May 2023)

American Society of Hematology

https://www.hematology.org/ (accessed 1 May 2023)

Association for Diagnostics & Laboratory Medicine (formerly American Association for Clinical Chemistry)

https://www.aacc.org/ (accessed 1 May 2023)

Association for Molecular Pathology

https://www.amp.org/ (accessed 1 May 2023)

Association for the Advancement of Blood and Biotherapies (formerly American Association of Blood Banks)

http://www.aabb.org (accessed 1 May 2023)

CDC

http://www.cdc.gov (accessed 1 May 2023)

Clinical Laboratory Management Association

https://www.clma.org/ (accessed 1 May 2023)

Clinical and Laboratory Standards Institute (CLSI)

http://www.clsi.org (accessed 1 May 2023)

(continued)

本书版权归John Wiley & Sons Inc.所有

APPENDIX 18.1 Regulations, Guidelines, and Information with Application to a Clinical Laboratory *(continued)*

College of American Pathologists (CAP)
http://www.cap.org (accessed 1 May 2023)

FDA
http://www.fda.gov/ (accessed 1 May 2023)

Federal Register
https://www.federalregister.gov/ (accessed 1 May 2023)

International Organization for Standardization (ISO)
http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm (accessed 1 May 2023)

The Joint Commission
http://www.jointcommission.org (accessed 1 May 2023)

APPENDIX 18.2 CAP Laboratory Inspection Checklist Associated with Quality Management

The following checklists are relevant to quality management; contents for each checklist are included. These reflect the CAP Accreditation Checklists, 2022 edition (https://documents.cap.org/documents/cap-accreditation-checklists.pdf; accessed 2 May 2023).

Checklist(s)	Subdisciplines[a]	Contents
All common	NA	Proficiency testing Policy and procedure manuals Specimen collection and handling Quality management Reporting of results Reagents Instruments and equipment maintenance/function checks Thermometers and temperature-dependent equipment and environments Pipettes and analytical balances Waived test implementation Test method validation/verification—nonwaived tests Individualized quality control plans
Biorepository	General specimen processing Specimen collection/procurement Specimen distribution and agreements Specimen informatics Specimen storage	Quality management Biospecimen collection and handling Biospecimen processing and quality, including DNA/RNA extraction/amplification, cell fractionization, cell and tissue culture, and histology Specialized techniques, such as whole slide imaging, digital image analysis, tissue microarray, laser capture microdissection, and molecular methods Inventory management system Storage Source and sponsor facilities Informed consent and institutional review board Distribution policies and agreements
Laboratory, general	NA	Quality management system Specimen collection Chain-of-custody specimen collection and handling Direct-to-consumer testing Specimen transport and tracking Result reporting Quality of water Laboratory computer services Telepathology and remote data assessment Whole-slide imaging Personnel Physical facilities Laboratory safety California laboratory licensure requirements

[a] NA, not applicable.

本书版权归John Wiley & Sons Inc.所有

19

Introduction
ISO Background
ISO Certification versus ISO Accreditation • "Shall"/"Should"/"May"/"Can" Explained
ISO 9001
Seven Principles of ISO 9001 • Standards Related to ISO 9001
ISO 15189
Structure of ISO 15189 • Important Principles of ISO 15189 • Documents Related to ISO 15189 • ISO 15189 versus ISO 9001 • CLIA '88 and ISO 15189 • International Requirements for ISO 15189 Accreditation • Considerations for the Laboratory Management Team • Approaching ISO 15189 Accreditation • Accreditation Bodies for ISO 15189 • CAP as an Accreditation Body
SUMMARY
KEY POINTS
REFERENCES

International Organization for Standardization

Anne Marsden and Amy Shahtout

OBJECTIVES

To provide an overview of the International Organization for Standardization

To describe the ISO standards most relevant in a clinical laboratory service setting

To elaborate on the technical and management requirements of ISO 15189

To describe the process for obtaining and maintaining ISO certification

Without continual growth and progress, such words as improvement, achievement, and success have no meaning.

Benjamin Franklin

A QUALITY MANAGEMENT SYSTEM (QMS) is the combination of organizational structure, resources, people, documents, and activities designed to ensure quality in an organization's products and services. It describes the coordinated activities needed to direct and control an organization with regard to its quality. These activities include the establishment of human and infrastructure resources for operations, well-planned processes designed to produce a product or service, identifying and monitoring the effectiveness of the plans, and continual improvement of those processes. Worldwide, the most widely adopted QMS regime is the ISO 9000 family. A related internationally recognized QMS stems from ISO 15189, which is tailored to clinical laboratories.

ISO Background

While ISO certification is voluntary in the United States, it serves as an attractive credential—especially for companies that intend to reach an international market—and demonstrates the intent to manage quality through practices deemed acceptable by the International Organization for Standardization (ISO). Conformance to standards contributes to higher quality, safety, reliability, and interchangeability of products and services. This potentially increases a company's marketability, customer retention, and acquisition of new customers.

Operating since 1947, the ISO is a nongovernmental association consisting of representatives from over 160 countries. There are approximately 3,000 ISO technical committees and working groups, with participation from about 50,000 experts, contributing to the development of ISO standards that provide the framework for compatible technology internationally. Efforts to achieve

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch19.

本书版权归John Wiley & Sons Inc.所有

technical consensus for each standard are coordinated by a central secretariat in Geneva, Switzerland. The organization's goal is to define quality standards for organizations to facilitate and promote the trade of products and services internationally. (Isos, Greek for "equal," is the basis for the organization's short name, ISO.) The standards are also used by some governments to establish health, safety, and environmental laws.

ISO/TC 176 was created in 1979 and produces the standards related to quality management and quality assurance. Its scope is generic quality management systems and sector-specific quality management systems at the request of the affected sector and the Technical Management Board. Subcommittee 2 (ISO/TC 176/SC2) is responsible for the development of ISO 9001, Quality Management Systems—Requirements.

ISO/TC 212 produces the standards related to clinical laboratory testing and *in vitro* diagnostic test systems. It was created in 1994 and is charged with standardization in the clinical laboratory, including quality management, pre- and postanalytical procedures, analytical performance, laboratory safety, reference systems, and quality assurance. It excludes generic quality management systems (which are addressed by ISO 9001) and medical devices (dealt with by ISO/TC 210, a separate committee). ISO/TC 212 prepared the standard known as ISO 15189, first published in 2003.

ISO 15189 is based on a more general standard, ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories. This standard is applicable to a wide range of testing services and is a well-known basis for certification and accreditation in many industries. ISO 15189 differs in that it addresses elements specific to the medical laboratory and to patient care.

Standards are generally reviewed every 5 to 7 years, and as outdated standards are withdrawn, new standards are issued. The revision date is indicated in the name of the document. The current standards under discussion in this chapter are ISO 9001:2015 and ISO 15189:2022.

ISO Certification versus ISO Accreditation

There is a significant difference between the terms "accreditation" and "certification." Certification is defined by ISO as the "[p]rocedure by which a third party gives written assurance that a product, process or service conforms to specific requirements." Certification addresses the quality management system, its documentation, and its processes (including corrective and preventive actions, internal audits, and so on). It does not address competence in operation or provision of the service. The accreditation process, in contrast, considers the quality management system and additionally has requirements for technical competence. Accreditation is defined by ISO as the "[p]rocedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks" (1). Certification to the ISO 9001 standard shows that a laboratory has met the requirements for a robust quality management system but does not necessarily show it has demonstrated competence in producing valid test results. In contrast, ISO 15189 is an accreditation standard, and provides assurance of the technical competence of the laboratory.

Bodies providing certification are called "certifying" or "certification" bodies, and they are in turn accredited to perform the work by an accreditation body. Each accreditation body provides a directory of certifying bodies that they have accredited. Examples of accrediting bodies include the ANSI National Accreditation Board (ANAB) (anabpd.ansi.org) and, in the United Kingdom, UKAS (ukas.com). A laboratory intending to become ISO 9001 certified will partner with a certifying body.

A laboratory working toward ISO 15189 accreditation may contact an accreditation body directly. Examples of U.S. accreditation bodies for ISO 15189 are the College of American Pathologists (CAP) (cap.org), A2LA (a2la.org/accreditation), and the Institute for Quality Management in Healthcare (IQMH) (iqmh.org).

"Shall"/"Should"/"May"/"Can" Explained

Of note when reading ISO standards: In these documents, "shall" denotes a requirement (it is to be read as "must"), "should" denotes a recommendation, "may" denotes consent, and "can" means a possibility or a capability.

ISO 9001

The quality standards in the ISO 9000 family focus on quality management and include generalized QMS requirements for manufacturing and service industries. Certification to ISO 9001 provides evidence that a laboratory has an effective quality management system including document control, research and development activities, and error prevention and detection capabilities.

Seven Principles of ISO 9001

The current edition of ISO 9001 (2) has adopted common terms and definitions from other quality management system standards. The high-level structure has changed from the previous edition, giving it a strong foundation of seven quality management principles: (i) customer focus; (ii) leadership; (iii) engagement of people; (iv) process approach; (v) improvement; (vi) evidence-based decision making; and (vii) relationship management. The standard is divided into 10 clauses. The first two, Normative References and Terms and Definitions, both refer the reader to ISO 9000:2015 for further information (3).

The terms "context of the organization" and the related "interested parties" are among the key concepts in quality

本书版权归John Wiley & Sons Inc.所有

management. To ensure sustained success, it is not sufficient for an organization to understand its core processes. It is important for the organization to comprehend the internal and external issues and the other parties that are relevant to its products, services, and strategic direction, to the extent that these impact its ability to achieve its intended results. "Interested parties" are defined as "those that provide significant risk to organizational sustainability if their needs and expectations are not met." These may include customers, investors, business partners, and—particularly for clinical laboratories—regulatory agencies.

Once the context of the organization is understood and defined, the organization can then move on to strategic planning and establishing brand identity. As ISO 9000 clarifies, this review is needed to help create "unity of purpose" and "align [the organization's] strategies, policies, processes and resources to achieve its objectives." The organization is to ensure the "engagement of people" with the QMS as part of this unity of purpose.

Another change brings ISO 9001 into closer alignment with other laboratory standards. Formerly, the emphasis was on the manufacture of products. The current standard explicitly supports both products and services. Product realization has been changed to "operation." The requirement for monitoring and measuring "equipment" has now changed to monitoring and measuring "resources." One relevant example would be customer surveys, as monitoring resources useful in determining the effectiveness of a clinical laboratory's QMS. Also, where language around nonconforming product used to imply that it was a physical object quarantined for disposition, now a nonconforming service in the laboratory (for example, a result released after published turnaround time) can be allocated a transaction number and sent for root cause investigation.

The leadership of the organization is expected to "tak[e] accountability for the effectiveness of the quality management system." This is a change from the previous edition, where leadership appointed a management representative. The top management of the organization is now responsible for ensuring that the QMS achieves its results and for promoting improvements in the system. This change is significant in bringing the standard into alignment with clinical laboratory practice, where a laboratory director is normally held responsible for the proper functioning of the clinical laboratory.

Current requirements include the maintenance of "organizational knowledge," which is to say information that the organization holds that is not in standard operating procedures and textbooks. Information can be maintained and transferred by training sessions, that is, meetings where issues related to the QMS are raised and discussed, corrective action notes are shared, and similar processes occur.

Change management is a major part of the standard. Most laboratories are now familiar with document control of standard operating procedures. Additionally, under ISO 9001, changes in product or service requirements, changes in the design of a product or service, changes in operation, and changes to the QMS itself must be planned and documented. The planned changes must be reviewed to ensure the product or service will continue to meet customer requirements, and records of the reviews and actions taken need to be documented.

Risk-based thinking is a foundation of the updated standards. In laboratory terms, one way to approach this is "preventive action." The organization must have a process to manage risk, including identifying where there are risks to their products, services, processes, and supplies and applying risk-mitigating measures to prevent problems from occurring or to minimize impact.

A major differentiator between ISO 9001 and the related laboratory standard, ISO 15189, is ISO 9001's requirement for "Design and development of products and services" (Section 8.3). A laboratory which modifies tests or develops new tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) may find the provisions of this section invaluable.

The standard requires that a design and development process be established, implemented, and maintained that is "appropriate to ensure the subsequent provision of products and services." In order to achieve this, it specifies a number of subprocesses including:

- Design and development planning; preplanning the stages of the project
- Involving customers in the initial planning process
- Considering the inputs to the process, which includes regulatory requirements and the potential consequences of failure of this product or service
- Defining the results to be achieved
- Verification that the inputs match the outputs
- Validation activities to ensure the product or service meets requirements
- Ensuring that changes made during or subsequent to design and development are controlled to prevent adverse impacts on the final product or service

Standards Related to ISO 9001

In addition to ISO 9001:2015—Quality management system requirements, it is recommended that a laboratory planning ISO 9001 certification obtain the following documents for reference purposes:

ISO 9000:2015 Quality management systems—Fundamentals and vocabulary

ISO 19011:2018 Guidelines for auditing management systems

本书版权归John Wiley & Sons Inc.所有

ISO 10002:2018 Quality management—Customer satisfaction—Guidelines for complaints handling in organizations

ISO 9004:2018 Quality management—Quality of an organization—Guidance to achieve sustained success

All ISO documents are available for purchase from the ISO at iso.org.

ISO 15189

First published in 2003, ISO 15189 (4) is based on ISO 9001 and a standard known as ISO/IEC 17025. It is an international standard specifically developed for medical laboratories. It is a longer document than ISO 9001, and the requirements are very detailed; to the QMS requirements of ISO 9001 it adds the technical and competency factors that are relevant to laboratories. It is the standard required for reimbursement in many countries.

Structure of ISO 15189

ISO 15189 is based on an older QMS standard, ISO/IEC 17025, and is influenced by the familiar CLSI guideline QMS01, "A Quality Management System Model for Laboratory Services" (5, 6).

The standard contains clauses that outline management requirements (including general management system requirements) and technical requirements (including preexamination, examination, postexamination, and postexamination process requirements).

An annex in the ISO 15189:2022 document provides a correlation matrix between ISO 9001:2015 and ISO 15189:2022.

The Web preview of the document (4) includes the table of contents, displaying the full structure of the standard.

Important Principles of ISO 15189

First and foremost, the organization must have a structure such that it can be held legally responsible for its activities, and there must be a laboratory director. The remaining structural, governance, and management system requirements are intended to guide effective management of the laboratory and its QMS by specifying such essentials as document control, internal audits, and corrective and preventive action. In addition to its legal and regulatory aspects, engaged and effective leadership is critical to the achievement of intended results, in both the business and clinical sense of the word.

Other clauses specify the technical aspects of the laboratory, including personnel training and competency assessment, provision of infrastructure, equipment calibration and repair, reagent acceptance, quality control materials, proficiency testing participation, specimen acceptance, examination procedures, result acceptance, and postexamination procedures.

Unlike ISO 9001, this standard uses the word "users" rather than "interested parties." Users "can include patients, clinicians, and other laboratories or institutions that send samples for examination," to which we may add pharmaceutical companies and regulatory bodies (4).

ISO 15189 states that "Laboratory management shall […] maintain processes for identifying risks of harm to patients and opportunities for improved patient care […] and develop actions to address both risks and opportunities for improvement." The standard itself does not give guidance but refers to ISO/TS 22367 (7). Risk management is preventive action writ large; an assessment of the likelihood and severity of potential risks should be undertaken, a plan drawn up, and the results monitored. If necessary, the plan is then updated (the Plan-Do-Check-Act Cycle) (8).

Nonconformities: Prevention and control of nonconformities is a large part of the ISO standard. "Nonconformity" is defined as "nonfulfillment of a requirement," and other terms are frequently used, including accident, adverse event, error, event, incident, occurrence, complaint, revised result, and amended result. Preventive action is action taken to forestall nonconformities. Inputs into the preventive action system may include risk analysis, trend analysis, and proficiency testing as well as reviews of prior nonconformities. The laboratory must have a system for identifying nonconformities as they occur, taking action to contain the issue (for example, to prevent the distribution of the error) and corrective action to prevent recurrence (including an analysis of the root cause of the incident). This system should feed back into the risk assessment system to prevent similar errors from occurring in other circumstances.

The standard requires verification (of FDA-approved/cleared tests used without modification) and validation (of modified tests and laboratory-developed tests [LDTs]). The language used is similar to that of CLIA '88 and, although of use to most laboratories, it is not sufficiently detailed for a laboratory wishing to design and bring online a testing menu with many "home-brew" LDTs. A laboratory which desires to do so may prefer to explore ISO 9001 certification, a significant proportion of which is dedicated to planning and realization (research and development) of products and services. (See above in this chapter.)

Test validation, per the standard, should encompass the performance characteristics of the test, one of which is measurement uncertainty. The estimate must be made available to customers upon request. The CAP defines

本书版权归John Wiley & Sons Inc.所有

measurement uncertainty (MU) as "The degree to which one is certain of results for a particular measurement/testing process, expressed as a confidence level within a range." CAP has stated that laboratories which are accredited by its Laboratory Accreditation Program (LAP) already have the information needed to produce these estimates from their quality control records, proficiency testing, calibration, instrument comparison, and method comparison, as well as any additional data supporting the analytical measurement range as defined by the laboratory director (9). For the purposes of ISO 15189, these data need to be documented in a compliant format. Pereira has a discussion on the meaning and significance of this performance characteristic (10).

Documents Related to ISO 15189

In addition to ISO 15189:2022, Medical laboratories—Requirements for quality and competence, it is recommended that a laboratory planning ISO 15189 accreditation obtain the following documents for reference purposes:

ISO 9000:2015 Quality management systems—Fundamentals and vocabulary

ISO 19011:2018 Guidelines for auditing management systems

CLSI guideline QMS01, "A Quality Management System Model for Laboratory Services," 5th edition (2019)

All ISO documents are available for purchase from the ISO at iso.org. CLSI documents are available from CLSI at clsi.org.

ISO 15189 versus ISO 9001

ISO 15189 has advantages over ISO 9001 in the clinical laboratory. The former is tailored to the laboratory, it uses more familiar vocabulary, and laboratories accredited to CLIA '88 standards will find themselves already partly compliant. Many countries have adopted ISO 15189 accreditation as a basis for laboratory accreditation. However, ISO 9001 may be preferred, particularly by international organizations, because of its long-standing multinational reputation. An ISO 9001 certification is recognizable and comprehensible by customers and interested parties all over the world. Additionally, it includes research and development of products and services, which may be of significant use to laboratories developing their own tests (LDTs).

CLIA '88 and ISO 15189

CLIA '88 (42 C.F.R. § 493 [11]) comprises the regulations in the United States that establish quality requirements for laboratory testing performed on specimens from humans, such as blood, body fluid, and tissue, for the purpose of diagnosis, prevention, or treatment of disease or assessment of health. Laboratories are required to meet these standards and have evidence of compliance.

ISO 15189 is an effective quality management system framework that highlights the laboratory's commitment to and promotes continual improvement. Accreditation to the standard demonstrates the laboratory's competency in testing. **By itself, ISO 15189 does not meet the federal criteria for accreditation (CLIA '88) in the United States, and other, compliant, laboratory accreditation must be maintained** (12).

International Requirements for ISO 15189 Accreditation

In the U.S., ISO 15189 accreditation is voluntary. In more than 60 countries, the ISO 15189 standard is a part of medical laboratory accreditation requirements. These countries include the United Kingdom, Canada, Mexico, Australia, France, Germany, Israel, Hong Kong, and the United Arab Emirates.

Acceptance of ISO 15189 as the standard for all laboratories is growing, but it is not universal. For Europe, one paper concludes, "While there are several variations in the approaches to accreditation of medical laboratories in the European countries, the ISO 15189 accreditation project has been widely accepted" (13). However, for Latin America, in 2018, one article stated, "The ISO 15189 standard, however, does not have especially high uptake in Latin America. Not only is the standard not mandatory, but other competing international standards are available to medical testing laboratories" (14).

Considerations for the Laboratory Management Team

In some countries, ISO 15189 accreditation is mandatory for clinical laboratories operating out of that country.

In countries where it is voluntary, advantages include:

- A well-understood quality management system (QMS) with copious documentation, supportive articles, and trained, experienced consultants
- A path to increasing maturity of the QMS
- An internationally recognized accreditation. Customers and interested parties in multiple countries accept the standard.
- An accreditation that provides evidence of technical competency as well as adherence to a QMS
- Assurances, with documentation, provided to external clients who are required to validate their reference laboratory in order to meet their own quality system requirements

本书版权归John Wiley & Sons Inc.所有

- Potential for cost avoidance from application of risk mitigation principles

ISO 15189 emphasizes process- and risk-based thinking as well as:

- An empowered employee culture
- Standardization of processes within and between departments
- Control of documents (a frequently cited deficiency in laboratories is inadequate document control, particularly for the use of unapproved and outdated work notes posted at benches)
- Root cause analysis leading to eradication of error types and their causes
- Emphasis on reduction in opportunities for error, replacing "blame the technologist" in error reports
- Change management (understanding the implications of a change before it is put into place)
- Monitoring the effectiveness of improvements that have been implemented

Laboratory leaders may be reluctant to spend the resources necessary to implement "yet another quality system" without a guarantee that it will bring improvements in patient care. Since many laboratories have already achieved ISO 15189 accreditation, write-ups on the lessons learned and improvements gained are available on the Web and in the laboratory press, detailing the pros and cons of accreditation (for example, see reference 15).

Major learnings can come from the initial stages: team formation, employee engagement, and gap analysis projects. The ongoing maintenance of accreditation can bring continual improvement in selected metrics, reduced errors, and increased efficiencies.

Approaching ISO 15189 Accreditation

Laboratories which currently do not follow a quality management system (such as QMS01 from CLSI [5]) may feel that implementation of an international standard will be arduous. It is important for each laboratory to know how much of a hill there is to climb.

One technique is a "gap analysis," where the laboratory internal requirements are assessed against the requirements in the ISO standard. A gap analysis is useful because it can be completed quickly (for example, during one internal audit session), but may not be helpful in addressing whether the elements of the QMS are linked effectively and work together as a whole.

Another technique is a "maturity assessment," which can be effective for assessing various attributes of a management system or culture. The assessment is often completed using a model with maturity level ratings, each level with its own description or criteria. For example, the highest maturity level achieved could reflect "best practice." The laboratory assesses the maturity of its processes to identify strengths and opportunities for improvement and uses the results to define a plan for increasing maturity.

The accrediting body selected by the laboratory may be able to provide analysis and assessment tools for initial assessments and preparation.

Some laboratories build on quality improvement systems they had previously adopted or put into place, for example, "Lean," which is a continual improvement methodology focused on increasing value to the customer, improving efficiency, and eliminating waste. Laboratories which have put together teams for Lean improvement state they have a head start on ISO 15189, in terms of a culture of employee engagement and a culture of improvement (15, 16).

A robust form of document control (whether electronic or paper-based) is a necessary foundation for implementation of ISO standards. Laboratories today should be familiar with the principle, which forbids the use of unauthorized or undated operating procedures and associated forms in the laboratory. Despite this, lack of control is frequently cited as a deficiency during audits and inspections (6). The causes of the deficiency are varied, but often come down to inadequate operating procedures which are then supplemented unofficially by notes on benches or in lab coat pockets. The opportunity can be taken to improve the operating procedures (and their associated forms) to current standards and ensure their usefulness by asking the staff working with them for their input. Once they are approved and put on an appropriate review cycle, the document controllers can turn their attention to other documents which require control under ISO 15189, including those for the QMS itself (for example, key measures and management review of error occurrences) and others (for example, validation or verification plans, results of validation or verification, and change management documents). If this process is in place, it takes care of a substantial proportion of the management requirements.

Accreditation Bodies for ISO 15189

A laboratory working toward ISO 15189 accreditation may contact an accreditation body directly with their query. Examples of accrediting bodies for ISO 15189 are CAP (cap.org), A2LA (a2la.org/accreditation), and IQMH (iqmh.org).

CAP as an Accreditation Body

CAP is an accreditation body which offers services to laboratories that are legal entities or part of a legal entity, have a defined and documented scope of services, and are in the CAP Laboratory Accreditation Program (LAP).

Once accredited, the laboratory is placed on a 3-year accreditation cycle. During the third year, a re-accreditation assessment is scheduled and performed. It is important to

本书版权归John Wiley & Sons Inc.所有

note that ISO 15189 accreditation does not replace the CAP LAP, which must be maintained. CAP provides details of its program on its website (17).

SUMMARY

ISO certification can be an attractive credential for a clinical laboratory. Although the ISO standards discussed here each provide a QMS framework, the ISO 9001 standard requires extensive interpretation, while ISO 15189 is written specifically for a medical laboratory setting. The CAP continues to play a role in the development of the ISO 15189 standard and, since 2008, has been an accrediting body for this standard. The certification or accreditation process is followed by ongoing maintenance of the QMS by the laboratory, as well as surveillance audits performed by the certifying body.

KEY POINTS

- ISO 9001 is a quality management system based on seven quality management principles.
- ISO 15189 provides a quality management system framework specific for medical laboratories.

REFERENCES

1. **Berwouts S, Morris MA, Dequeker E**. 2010. Approaches to quality management and accreditation in a genetic testing laboratory. *Eur J Hum Genet* **18**(Suppl 1):S1–S19.

2. **International Organization for Standardization**. 2015. ISO 9001:2015 Quality management systems—Requirements. https://www.iso.org/standard/62085.html. Accessed 30 July 2023.

3. **International Organization for Standardization**. 2015. ISO 9000:2015 Quality management systems—Fundamentals and vocabulary. https://www.iso.org/standard/45481.html. Accessed 30 July 2023.

4. **International Organization for Standardization**. 2022. ISO 15189:2022 Medical laboratories—Requirements for quality and competence. https://www.iso.org/standard/76677.html. Accessed 30 July 2023.

5. **Clinical and Laboratory Standards Institute**. 2019. A quality management system model for laboratory services. 5th ed. QMS01. CLSI, Wayne, PA.

6. **Schneider F, Maurer C, Friedberg RC**. 2017. International Organization for Standardization (ISO) 15189. *Ann Lab Med* **37**:365–370.

7. **International Organization for Standardization**. 2020. ISO/TS 22367:2020 Medical laboratories–Application of risk management to medical laboratories. https://www.iso.org/standard/71254.html. Accessed 30 July 2023.

8. **ASQ. 2023**. What is the Plan-Do-Check-Act cycle? https://asq.org/quality-resources/pdca-cycle. Accessed 30 July 2023.

9. **College of American Pathologists**. 2015. Measurement uncertainty guide: ISO 15189 Accreditation Program. documents.cap.org/documents/cap15189-accreditation-program-measurement-uncertainty-guide.pdf. Accessed 30 July 2023.

10. **Pereira P.** 2017. ISO series update, Part 2: 15189:2012 Medical laboratories - Requirements for quality and competence. Westgard QC, Madison, WI. www.westgard.com/iso-15189-2012-requirements-1.htm. Accessed 30 July 2023.

11. **Code of Federal Regulations**. 2023. Clinical Laboratory Improvement Amendments (CLIA '88) 42 C.F.R. Part 493 (1992). https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493. Accessed 30 July 2023.

12. **College of American Pathologists**. 2023. CAP 15189 Accreditation Program Frequently Asked Questions. https://www.cap.org/laboratory-improvement/accreditation/cap-15189-accreditation-program/cap-15189-accreditation-program-frequently-asked-questions. Accessed 30 July 2023.

13. **Boursier G, Vukasovic I, Brguljan PM, Lohmander M, Ghita I, Bernabeu Andreu FA, Barrett E, Brugnoni D, Kroupis C, Sprongl L, Thelen MHM, Vanstapel F, Vodnik T, Huisman W, Vaubourdolle M**, Working Group Accreditation and ISO/CEN standards (WG-A/ISO) of the EFLM. 2016. Accreditation process in European countries—an EFLM survey. *Clin Chem Lab Med* **54**:545–551.

14. **Sector & Segment**. 2022. Current review of clinical testing compliance to global standards in Latin America. https://sectorandsegment.com/current-review-of-clinical-testing-compliance-to-global-standards-in-latin-america/. Accessed 30 July 2023.

15. **Ford A.** 2015. Henry Ford: Using ISO 15189 to Change Patient Care for the Better. College of American Pathologists. documents.cap.org/documents/ford-using-iso15189-patient-care.pdf. Accessed 30 July 2023.

16. **Ford A.** 2014. ProMedica: Getting to the root of the problem. College of American Pathologists. documents.cap.org/documents/promedica-getting-to-root-of-problem-iso15189.pdf. Accessed 30 July 2023.

17. **College of American Pathologists**. 2023. CAP 15189 accreditation process. cap.org/laboratory-improvement/accreditation/cap-15189-accreditation-program/cap-15189-accreditation-process. Accessed 30 July 2023.

本书版权归John Wiley & Sons Inc.所有

20

Introduction
Delivering the Message
Communicating to Diverse Audiences
Means and Mechanics of Effective Communication
Spoken Word • Written Word • Intradepartmental Communication • Interdepartmental Communication • External Communication
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENT
REFERENCES

Effective Communication in Laboratory Management

Andrea Linscott and Elise Occhipinti

OBJECTIVES

To describe the importance of effective communication to laboratory management

To identify the recipients of laboratory communication

To discuss the means and methods of communication

The newest computer can merely compound, at speed, the oldest problem in the relations between human beings, and in the end the communicator will be confronted with the old problem, of what to say and how to say it.

EDWARD R. MURROW

IN THIS ERA OF INFORMATION OVERLOAD, effective communication is one of the most important skills needed in pathology and clinical laboratories. Seventy percent of medical decisions hinge on the interpretation of laboratory data (1). Laboratorians are stewards of these data and therefore have the responsibility of ensuring they are transmitted clearly and effectively. The COVID-19 pandemic and its ensuing focus on diagnostics have propelled laboratory services from the proverbial "basement" into the forefront of hospital operations. The renewed focus on laboratory services collided with many healthcare systems implementing the 21st Century Cures Act requirements into their care delivery model (2). This legislation requires that patients have immediate open access to their laboratory data. As a result, laboratories must tailor data delivery models to a vast audience of healthcare providers, other laboratorians, patients, caregivers, insurers, and hospital administrators. This requires an organized, systematic, flexible, and bidirectional exchange of information, ideas, standards, and beliefs between the laboratory and its customers, i.e., effective communication.

Communication can be defined a number of ways:

- The exchange of thoughts, messages, or information using speech, signals, writing, or behavior (3)
- The art and technique of using words effectively to impart information or ideas (3)
- A system, such as mail, telephone, television, or computer, for sending and receiving messages (3)
- The exchange or transmission of ideas, attitudes, or beliefs between individuals or groups (4)

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch20.

本书版权归John Wiley & Sons Inc.所有

The importance of communication has been discussed and documented since formal management theories were first promulgated. Chester I. Barnard wrote in 1938 in *Functions of the Executive* that the first executive function is to develop and maintain a system of communication (5). Management textbooks have devoted chapters to the need for effective communication. In *The Management of Organizations*, Hicks (6) stated, "Organizational interaction depends on communication. . . . Communication is of prime concern to managers because it makes cooperative action possible." It was his belief that as one moved up any management structure, more time had to be devoted to communication to succeed. Because he taught that "communication is a primary requirement of decision making," it was the only way to achieve any change in direction or activity of the company or institution.

As management theory evolved, the importance of communication grew. Peters and Waterman, in *In Search of Excellence* (7), state, "The nature and uses of communication in excellent companies are remarkably different from those of their nonexcellent peers. The excellent companies are a vast network of informal, open communications." The results of constant communication include getting the right people together and maintaining the continuous transmission of ideas and information. Peters and Waterman (7) say, "The intensity of communications is unmistakable in the excellent companies." If laboratories are to provide excellent service, i.e., function as excellent companies for their clients, communication should still be the first priority of everyone in laboratory management.

Communication within healthcare, or the lack thereof, is a major focus of two reports from the Institute of Medicine (IOM): *To Err Is Human: Building a Safer Healthcare System* (8) and *Crossing the Quality Chasm: A New Health System for the 21st Century* (9). The reports discuss the inefficient flow of information within health systems and the misconception that the need for privacy has been translated into secrecy, thus severely compromising the sharing of information. In an environment where patient safety is of highest priority, laboratory management must strive to provide not only diagnostic accuracy, but also must present patient testing information in a transparent and concise manner. However, these essential skills are not routinely mentioned in the curricula for physician and nonphysician laboratorians. In fact, communication among members of the healthcare "team" is generally not taught at all. The IOM study (8) states, "Because medical training is typically isolated from the training of other health professionals, people have not learned to work together to share authority and collaborate in problem solving." The same can be said for the training of all health professionals. It is rare to find an interdisciplinary course on communication and problem solving in any allied health school. The health professions that commonly interact with the patient and other members of the healthcare team often develop their communication skills on the job. This opportunity does not often present itself to laboratorians, who tend to function in a more isolated or "behind the scenes" role in patient care.

Information flow throughout the healthcare setting is complicated. Information must be exchanged between the patient and their care team, internal and external departments, vendors, and regulatory agencies in a multidirectional fashion. When information flows efficiently, the functionality of the laboratory is enhanced. For instance, if ordering providers in the client base (hospital, system, network, etc.) have clear access to what tests the laboratory offers, when they are performed, and the expected turnaround time (TAT), the service center will field fewer rote phone calls. The service center will be able to focus on effectively routing technical questions and solving logistical challenges in real time.

It is the responsibility of laboratory management to ensure that the information flow is bidirectional, concise, and predictable. The widespread adoption of the electronic medical record (EMR) and physician order entry has generated a steep escalation in the number of electronic messages that healthcare providers field on a daily basis. These messages reach the provider primarily via the EMR, secure text, emails, and patient portals. Because of the sheer volume and demand for timely response, redundant or ineffective communications will be overlooked. The laboratory must tailor communications to the urgency of the situation and should have a similar mechanism to receive feedback from its clients. Crucial escalations/events should be easily identifiable to the client and used sparingly by the laboratory. For example, in the case of a critical laboratory value, the provider and laboratory should be able to communicate with each other through multiple methods such as electronic messaging and telephone calls. The urgency of the message should be immediately apparent and not lost in a tsunami of less critical communications.

Delivering the Message

Management should have a communication strategy—a plan that is used whenever the laboratory has information that it wants to disseminate (Table 20.1). This plan should first identify the specific purposes for communication. The purposes should include the education of all clients on:

- The appropriate utilization of laboratory services (test orders, frequency of test orders, specimen collection and transport, testing turnaround times, report formats, additional report comments, reference ranges, consultation options, and test limitations)
- The extent of services offered (test menu, test available for STAT testing, and comprehensive test parameters)
- Regulations concerning the operation of the laboratory as well as any mandated communication (hours of operation, performance of tests per shift, STAT reporting, critical value reporting, and laboratory organization chart)

本书版权归John Wiley & Sons Inc.所有

Table 20.1 Elements of a communication plan

Define objectives and purpose of the plan.
Use a concise message.
Gear communication to education level of recipient.
Identify the structure and format of written communiqués.
Design a format and use it as a template for all written communications.
List recipients of laboratory communication.
Identify all stakeholders who should receive communication (medical staff, laboratory staff, administration, clients, computer services, patients, etc.).
Identify the method(s) of communication.
Written (memo, newsletter, email, electronic message, specimen collection manual, etc.), verbal (phone call, intercom, etc.) or visual (banner, poster, video, etc.)

The plan should also contain the formal structure or format of all written communiqués such as memos, newsletters, and flyers. Once a uniform look and feel of the written word has been adopted, all written notifications from the laboratory will convey an image and eventually establish an identity for the department. The plan should also include the elements of the strategy, i.e., with whom the laboratory believes the information will be shared, the mechanics of communication that the laboratory will use, and the purpose of communication. Communication should be considered a way of marketing the laboratory and its services, and a well-constructed plan will aid in that marketing by focusing the message. Whether the memorandum is about a protocol, a new test, a change in procedure, or a new service, the information should be presented so that the laboratory's expertise and its concern for its customers are obvious. Done properly, effective communication can be a competitive advantage.

Communicating to Diverse Audiences

Effective laboratories will communicate with each of their customers: physicians, nursing and allied health professionals, patients, third-party payors, etc. Each of these entities has unique needs and processes information differently. As Hicks (6) states, "A person may not communicate with his supervisor in the same manner that he does with a person of equal standing." Adapting that statement to laboratories means that the laboratory manager may not tell the hospital administrator about federal rules and regulations in the same fashion used to inform the staff of each department. Indeed, the actual information that the hospital administrator needs to know will be different from that required by the staff. It is incumbent on the laboratory manager to tailor the message to each audience so that the message is understood.

Boyett and Boyett (10) implore managers to communicate, communicate, communicate, and communicate some more. There is really no such thing as too much communication. Clients will only perceive that there is too much communication if the information is superficial or not pertinent to their needs.

Unannounced visits from the healthcare team should be treated as opportunities to exchange information. This can also be accomplished by guided tours targeted for select physician or administrative groups. The successful laboratories are often those in which clinicians can be found looking through microscopes in hematology, microbiology, and pathology and consulting with the staff. These laboratories are highly valued and perceived as very credible sources of important, accurate information. Heller (11) wrote, "For successful operations, information must be totally visible." Laboratories that open their doors to their customers will be successful and valued as integral members of the patient's healthcare team.

Laboratories communicate to convey information about policies and procedures (including rules and regulations that determine policies), results of tests ordered, status of testing, and new technology and services that are being added or tests that are being discontinued. The job of all managers is to coordinate the human and physical elements of an organization into an efficient and effective working unit. Communication is of prime concern to managers because it makes cooperative action possible (6).

Means and Mechanics of Effective Communication

Heller (12) wrote, "For effective communication, you must be aware of the means and the channels . . . with which to transmit and exchange information" (Table 20.2). The means of communication are fairly simple: the spoken word, the written word, and visual images. The mechanics include EMR alerts, written memoranda, emails, text or secure messaging, reports, notices, newsletters, flyers, telephone or beeper service, manuals, formal presentations, etc. The trick is to match the mechanics to the message so that the message is well received. For instance, many laboratories produce a handbook that describes all of the tests they offer (test menus), with information about the specimen requirements, expected TATs, indications for ordering, and reference ranges. While this is an excellent communication device for anyone needing laboratory services, it is not always used effectively. In many instances, the reason that this effort does not achieve the intended results is that the document is cumbersome and difficult to access. The individuals needing the information in this handbook are the very people who do not have the time to read it. Many laboratories have therefore digitized their handbooks and integrated them into the institutional

Table 20.2 Methods of communication

Action	Examples
Verbal	Telephone, face-to-face, video meeting
Written	Memoranda, email, newsletter, flyer, manual
Visual	Videos, posters, presentation, personal digital assistants

本书版权归John Wiley & Sons Inc.所有

Web page or EMR. This allows clinicians to seamlessly access the laboratory information in the course of their daily workflow. Another invaluable communication tool is incorporating job aids already familiar to the healthcare team (e.g., wall charts, EMR, systemwide message boards, etc.) and employing that mechanism to transfer information.

Any type of communication can be misinterpreted or contain errors. That is a risk that must be understood, but it should not impede the flow of information. The IOM's reports remind us that the majority of medical errors occur because of a lack of an open flow of information (8, 9).

Spoken Word

While we may not realize it, communication via the spoken word occurs daily in our laboratories—every time someone answers the phone. This is the most direct means of communication, but it can be the most damaging if words are not chosen carefully and if tone is not modulated. In our society of instant information, it is necessary to educate laboratorians in the use of the spoken word. Much can be accomplished with a telephone exchange or the clinician-laboratorian encounter in the laboratory if the words are carefully chosen, if body language and facial expressions are positive, and if we state our knowledge clearly without a great deal of laboratory shorthand that may be misunderstood by other members of the healthcare team. Scripting can be used to deliver a concise message when information or questions are routinely asked, for example, questions asked to verify a patient's name and medical record number or when relaying information about testing delays. Staff and management should be encouraged to engage caregivers in a discussion of the tests, the appropriateness of the tests, and the meaning of the results based on their level of knowledge. Each level of staff should be trained in consultation techniques and when to refer the provider to the next level of expertise. The traditional policy that no one other than the physician communicates information to other physicians is no longer workable given the increasing amount of information that needs to be communicated. However, it is necessary that laboratory personnel continually receive updated information that is relevant and appropriate for their job level, thus expanding the laboratory's consultative services.

It is the responsibility of the laboratory management to provide continuing education opportunities, both in-house and through external meetings, to improve the verbal skills and knowledge level of its personnel. It is not appropriate to rely on self-study modules to improve verbal skills. While self-study continuing education can be very efficient for the transfer of new scientific knowledge, it does nothing to enhance verbal skills because there is no verbalization going on. In this day of personnel shortages, it is difficult to free employees to attend meetings, in-house or externally. However, if one considers the payback when employees become adept at the spoken word and the laboratory's image and usefulness are improved, the sacrifices needed to send them to meetings will be worth it.

Written Word

As Heller (12) states, "The written word is the basis of organizational communication and . . . is relatively permanent and accessible." Written communications must be designed to optimize readability. The physical layout of the message should be constructed with standard fonts and font sizes. The page should not be crowded—the reader will be overwhelmed with the amount of information and either will not read it or will only skim it, potentially overlooking important information. Resist the urge to crowd the page with clip art or other images unless the visual image is guaranteed to enhance message delivery. Since all written communications are retrievable, it is important to confirm message clarity and completeness for the intended audience. These communications should never be be written and/or sent in haste, but thoroughly reviewed prior to sending. It is important to remember that all written documents, emails included, can be used as evidence (13).

The sender should stick to the facts and what he or she knows, without embellishments (13).

Intradepartmental Communication

Laboratory managers must encourage a routine exchange of thoughts and messages between the laboratory departments, management and staff, and different shifts. Management of critical events such as unexpected system downtimes should be hardwired, be simple to activate, and easily reach the target audience. The laboratory's organizational structure is based on the disciplines of pathology and laboratory science, which may not always be conducive to an open flow of information. Many laboratories use established intranets—communication superhighways for internal information exchange.

Without good internal communication, the potential for error increases. It is common for one department or shift to be unaware of new announcements concerning testing or schedules that were disseminated to the laboratory's customers. Laboratory managers may mistakenly assume that because the testing will not occur on that shift or in that department, for instance, that all personnel do not need to know about the changes. Because your customers (e.g., nurses, physicians, outpatients) read memos at any time of the day and night, you cannot predict when or to whom a query will be addressed. Written intradepartmental communication is very effective because there is documentation that it occurred and it can reach every shift and all staff, whether they were present on the day it was issued or not. However, communication should not be

本书版权归John Wiley & Sons Inc.所有

exclusively in the written form. Meetings, informal chats, and impromptu announcements allow the staff to ask questions and exchange ideas immediately. This active communication can improve staff morale, as personnel know that they are being heard.

Interdepartmental Communication

The flow of communication beyond the laboratory includes that between the laboratory and the institution's administration (whether it is the vice president of clinical services or the office manager in a physician's office) and its clients (e.g., patients, physicians, and nonphysician caregivers). Written interdepartmental communication tends to be more formal than intradepartmental and needs to be carefully structured.

Memos, letters, and notices are adequate forms of communication for most announcements and responses to inquiries from other departments of the institution. However, when laboratory management wants to start a new service, change protocols, discontinue a test, acquire instrumentation, or reorganize any part of the business, they should communicate through formal proposals (Table 20.3). Structuring a request this way ensures that you will address all of the questions that the reader may have. Before you write the proposal, you need to fully understand the missions and strategies of your institution. Your proposal should always point out how it will fulfill or complement the missions and strategies of the organization, particularly related to patient care. The components of a proposal, or a business plan, should (i) explain why the change or plan is needed and how it will contribute to the strategies of the overall institution/business (e.g., economic benefits, objectives); (ii) estimate the resources required, the cost of the program, revenues from the plan, and the timeline for completion, and identify the individual responsible for completion of the proposal; (iii) produce an outline of a plan of action; and (iv) describe what success will look like. If you cannot verbalize or quantify outcomes, the project will not be noticed and probably will not be approved.

Table 20.3 Elements of a formal proposal to change laboratory services

Identify the benefits to the organization.
Better patient care (e.g., quicker TAT, better test sensitivity, lower limits of detection)
Better patient safety (e.g., less toxic ingredients in specimen collection devices, needles with shield guards to prevent needle sticks)
Lean (e.g., less technologist time, better throughput)
Identify project-required resources, costs, and revenues.
Cost saving may also include less technologist hands-on time.
Specify the responsible individual.
Identify owner of the project who is responsible for making sure that all stakeholders (medical staff, laboratory staff, administration, clients, information service, and/or patients) are notified.
Communicate project completion timelines for implementation of the service.
Communicate any delays in the timeline to the appropriate stakeholder.
Describe the final outcome.
Put procedures in place for periodic review and revision, if necessary.

External Communication

Entities external to the organization include insurance companies, the federal government, accrediting agencies, competitors, and others. There are myriad regulations that affect a laboratory's operation, such as a license to operate and personnel policies. The federal government requires that every laboratory performing tests for diagnostic purposes be certified by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments of 1988. Laboratory managers must continuously remain current with these federal rules and regulations and must communicate any changes to their superiors. The changing rules for Medicare reimbursement also require monitoring and reporting up the chain of management. In addition, clinical laboratories are required by the Centers for Medicare and Medicaid Services to have a compliance plan (Health Insurance Portability and Accountability Act) that helps employees avoid actions that might be construed as fraud and abuse. The Office of the Inspector General has outlined what that compliance plan should look like. The human resources department in most institutions dictates personnel policies that must be followed in the laboratory.

The manner in which individuals communicate depends upon the formal organizational structure. In an organization that is rigidly structured, individuals will act and interact differently than in an organization that is very informal. The organizational chart will define how and with whom a manager will communicate; however, actual communication channels do not always strictly adhere to the organizational chart.

The most important activity that laboratory managers should undertake is to get out of the office and out of the laboratory. Managers should volunteer to serve on hospital committees and should encourage their staff to do so as appropriate. "Management by walking about" (MBWA) contributes to informal communication. As a manager from Hewlett Packard (identified as an excellent company) stated, "We just plain talk to each other a lot without a lot of paper or formal rigmarole" (7). The lesson from all successful companies is that management must be visible. Sitting in the laboratory, monitoring TATs, quality assurance, compliance, and billing, while essential to keeping the laboratory functioning, will not achieve the goals of a

本书版权归John Wiley & Sons Inc.所有

good communication system. Laboratory managers should practice MBWA, not just in the laboratory but also in the institution of which the laboratory is a part. The informal communication that occurs will be of immeasurable benefit to the laboratory as a whole. As nurses, physicians, patients, patients' families, and the institution's management begin to recognize the laboratory management, additional impromptu communication will occur. Managers should visit the nursing units (or any departments in which patients/customers are using the laboratory's services) on a routine, predictable basis. The agenda of these visits should include but not be limited to checking on the phlebotomy service, satisfaction with TATs, and the interpretation of laboratory reports.

As care providers come to know that the laboratory is interested in its performance, the department will be increasingly perceived as a member of the team. Some hospital laboratories have assigned personnel to a nursing unit or department so that there is a recognizable liaison with whom caregivers can readily communicate.

The laboratory should survey its clients periodically to determine how they get the majority of their information and what information they routinely need. The survey results will also tell management whether the services the laboratory is providing are pertinent and can be used to identify future services. All avenues for communication with people who interact with the laboratory should be explored and used to improve laboratory services.

SUMMARY

Communication is the exchange of ideas, attitudes, and information through the spoken word, written word, and visual images. Communication should be targeted to a specific audience and understood by that audience and can be delivered by myriad methods (e.g., telephone, fax, newsletters, manuals, internet, videos, etc.). Choose words wisely and never send communications in haste. Effective communication is a critical skill that laboratorians need to ensure effective delivery of laboratory services. It must be bidirectional between the laboratory and its customers, clients, and members of the organization's hierarchy.

KEY POINTS

- Effective communication, whether internal or external to the organization, is critical to the management of the laboratory.
- Communication must be tailored to the understanding and needs of its audience.
- Communication occurs by the written word, the spoken word, and visual images.
- Written and visual communications should be carefully reviewed before dissemination.

GLOSSARY

21st Century Cures Act A law designed to accelerate medical product development and advances for patients who need them faster and more efficiently.

Communication Exchange of thoughts, messages, or information (through speech, signals, writing, or behavior); art and technique of using words effectively to impart information or ideas; system, such as mail, email, telephone, or television, for sending and receiving messages; exchange or transmission of ideas, attitudes, or beliefs between individuals or groups.

External communication Occurs with entities outside of the organization (e.g., insurance companies, regulatory agencies, accreditation organizations).

Health Insurance Portability and Accountability Act (HIPAA) A federal law that protects patient health information from being disclosed without the patient's consent.

Hierarchy A group of individuals organized or classified according to rank or authority.

Interdepartmental communication Occurs between the laboratory and other organizational departments, clients, and healthcare providers. Tends to be structured and formal.

Intradepartmental communication Occurs within the laboratory between management, sections or divisions, and work shifts. Tends to be informal.

Management by walking about (MBWA) A process that promotes informal communication between managers and employees.

Quality assurance A systematic approach to continuously analyzing, improving, and reexamining the total testing process.

Turnaround time (TAT) The interval between the beginning of one event and the end of another event in the total testing process.

ACKNOWLEDGMENT

The authors would like to acknowledge the past contributions to this chapter from a previous author, Elissa Passiment.

REFERENCES

1. **CDC, Division of Laboratory Systems**. 2018. Strengthening clinical laboratories. https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html. Accessed 12 July 2022.

2. **U.S. Food and Drug Administration**. 2020. 21st Century Cures Act.https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act. Accessed 16 September 2022.

3. **American Heritage Dictionary of the English Language**. 2022. https://ahdictionary.com/word/search.html?q=Communication. Accessed 7 July 2022.

4. **American Heritage Dictionary**. 2022. Communication. *American Heritage Dictionary of the English Language*, 5th ed. HarperCollins Publishers.

本书版权归John Wiley & Sons Inc.所有

5. **Barnard CI**. 1938. *Functions of the Executive*. Harvard University Press, Cambridge, MA.

6. **Hicks H.** 1976. *The Management of Organizations*. McGraw-Hill Book Company, New York, NY.

7. **Peters TJ**, **Waterman RH Jr.** 1982. *Search of Excellence: Lessons from America's Best-Run Companies*. HarperCollins, New York, NY.

8. **Institute of Medicine (US) Committee on Quality of Health Care in America, Kohn LT, Corrigan JM, Donaldson MS (ed)**. 2000. *To Err is Human: Building a Safer Healthcare System*. National Academies Press (US), Washington, DC.

9. **Institute of Medicine (US) Committee on Quality of Health Care in America**. 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century*. National Academies Press (US), Washington, DC.

10. **Boyett J**, **Boyett J**. 2000. *The Guru Guide: The Best Ideas of the Top Management Thinkers*. Wiley, New York, NY.

11. **Heller R.** 2002. *Manager's Handbook: Everything You Need to Know about How Business and Management Work*. DK Publishing, Inc, New York, NY.

12. **Heller R.** 1999. *DK Essential Managers: Communicate Clearly*. DK Publishing, Inc, New York, NY.

13. **McGrath PJ**, **Scharff CM**. 2012. Think before you send: the legal risks in casual e-mail. https://www.forbes.com/sites/ciocentral/2012/06/06/think-before-you-send-the-legal-risks-in-casual-e-mail. Accessed 2 October 2022.

本书版权归John Wiley & Sons Inc.所有

21

Introduction
A Primer on Computers
Hardware • Software • Networking • Cloud Computing
Healthcare Information Systems
Laboratory Information System Fundamentals
LIS Architecture • LIS Interfaces • LIS Administration • LIS Selection and Implementation
Specialty Considerations
Microbiology • Blood Banking • Point-of-Care Testing • Molecular Diagnostics
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENTS
REFERENCES

Laboratory Information Systems

Melinda L. Doherty and Kenneth E. Youens

OBJECTIVES

To review basic principles of computing relevant to laboratory information systems (LISes)

To describe the key functionality of LISes

To explain the major concepts of LIS administration, including how LISes fit into the larger healthcare information system landscape

To discuss major specialty-specific considerations of LISes

Information is the lifeblood of medicine, and health information technology is destined to be the circulatory system for that information.

David Blumenthal, MD, MPP, National Coordinator for Health Information Technology

Modern laboratory information systems (LISes) are computer systems fundamental to clinical laboratory operations. They directly manage the workflow within the laboratory, handle reporting, and facilitate the day-to-day activities associated with generating test results (1). Since their appearance in the 1970s as rudimentary, arcane, and/or home-grown systems, LISes have become ever more complex and sophisticated (2).

In the preanalytic phase, the LIS plays a role in test order management, specimen collection, and specimen receipt into the laboratory. In most settings, laboratory orders are placed electronically and are transmitted into the LIS over an electronic interface. In settings where laboratory orders are submitted on paper forms, orders are transcribed into the LIS by laboratory personnel as part of the receiving process. Most LISes can create phlebotomy worklists to guide phlebotomists in collecting the appropriate numbers and types of specimens needed to perform each ordered test at the intended time. Upon receiving specimens in the laboratory, personnel use the LIS to generate specimen labels and to match specimens to their corresponding electronic test orders. In some cases, electronic health records (EHRs) produce LIS-compatible barcode labels at the time of specimen collection, reducing the need for specimen relabeling upon receipt in the laboratory.

During the analytic phase, the LIS supports specimen and test distribution, test analysis and interpretation, and results entry. Once specimens and orders have been received, the LIS routes the orders onto worklists corresponding to specific laboratory work locations and/or interfaced instruments. If necessary, the LIS can generate labels for and track subdivided samples (aliquots).

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch21.

本书版权归John Wiley & Sons Inc.所有

For testing performed on interfaced instruments, the instruments read barcodes on the specimen labels, perform the appropriate testing on each sample according to the orders transmitted from the LIS, and return results to the LIS when testing is complete. For testing performed manually or on noninterfaced instruments, personnel manually perform the testing or manually instruct instruments to perform the testing indicated on the LIS worklist for that work location or instrument. Once results are ready, personnel manually enter results into the LIS. The LIS may also include functionality to manage additional actions to be performed based on specific test results. For example, the LIS may automatically initiate reflex testing, where a new order is generated for a follow-up test if initial test results meet certain criteria. The LIS may also perform autoverification, where the LIS uses predefined criteria to sort results ready for release without further review from those requiring manual review (3).

In the postanalytic phase, the LIS is the primary tool for reporting. The LIS may be used to generate printed reports or to send reports across electronic interfaces for display in other electronic systems. The LIS may be configured to add interpretive information to results such as comments and abnormal flags. Report comments may be automatically appended by the LIS to test results, or they can be *ad hoc* text statements created on the spot for a particular patient. In addition to explaining the implication of test results, interpretive comments can suggest follow-up tests that may be ordered to better understand a patient's medical situation.

Clinical laboratories depend on the LIS for more than just these core elements of the three phases of laboratory testing. The LIS can be used to manage the quality control and quality assurance activities of the laboratory and monitor the inventory of laboratory supplies (4). LISes are used to generate management and financial reports to improve business processes and reduce waste (5). LISes are also used to manage and store data needed to meet laboratory regulatory and public health reporting requirements. Some LISes include customer relationship management (CRM) functionality to facilitate client interactions by, for example, creating client-specific financial and operational reports, identifying client-specific ordering and reporting trends, and tracking communications between clients and laboratory representatives.

In the remainder of this chapter, some basic computing background and key elements of laboratory information systems are discussed in more detail.

A Primer on Computers

At a basic level, computers are programmable devices that use hardware and software to store, retrieve, and process data. Computers are often digitally interconnected into networks that permit them to communicate and share resources. The operation of any modern laboratory relies heavily on computers and networking, so it is useful to have some understanding of the basic principles.

Hardware

Each of a computer's components is attached to a motherboard that connects, powers, and allows communication between the different parts. The central processing unit (CPU) is the "brain" of the computer and carries out the instructions of a computer program by performing calculations and logical operations. The CPU accesses and saves information in memory. Random access memory (RAM) is a type of fast, short-term memory where temporary information is stored. It can be considered the computer's "working memory." Read-only memory (ROM) is (semi) permanent storage which may be used to store instructions for initializing hardware and software during computer startup. Secondary storage devices like hard disk drives, CD-ROMs, and USB flash drives store software and user data. These devices retain information even when powered off and are well suited for storing large amounts of information. Computers may be connected to peripheral devices such as displays, printers, keyboards, and mice, via standardized hardware and communication protocols such as Universal Serial Bus (USB) or IEE1394 (FireWire).

The above basic components can be assembled in different configurations to make various types of computers. The most common classes of computers used in modern healthcare organizations are servers and workstations. Servers are computers that simultaneously provide functionality to multiple other programs or devices called clients. Most servers are powerful computers with fault-tolerant designs meant to maximize their availability and uptime. They are often housed in data centers and may be arrayed in clusters to provide redundancy and increase their computing capacity. Workstations, by contrast, are usually designed to be used by a single end user at a time. They are usually configured in a desktop form, with a high-resolution display and an attached keyboard and mouse.

Software

Software is the sets of instructions, i.e., programs, that tell a computer what to do. A computer's operating system is the software that manages and coordinates the function of the computer hardware, memory, and other processes, providing a consistent interface between the computer's hardware and the applications it runs. Common examples include Windows, MacOS, and various Unix-like operating systems such as Linux, FreeBSD, and Unix. A device driver is software that provides an interface between the operating system and a hardware device attached to the

本书版权归John Wiley & Sons Inc.所有

computer. Utility software includes programs run by users to help configure or maintain the computer, such as antivirus software, file managers, debugging software, and system monitoring software. Together, the computer's operating system, drivers, utility software, and other programs related to the functioning of the computer itself are referred to as system software. By contrast, application software is programs run on the computer to carry out specific tasks other than the operation of the computer itself. This broad category includes the enormous landscape of different programs familiar to end users, such as word processors, games, Web browsers, and spreadsheets. Database management systems are specialized application software that access and modify organized digital collections of data called databases.

Networking

Networking refers to interconnections between computing devices that allow the devices to share information with one another over wired or radio (wireless) connections. Specialized hardware like bridges, hubs, switches, repeaters, access points, and cabling is used to create the physical structure of the network and to ensure that data are transmitted correctly. Network interface controllers (NICs) are used to connect computers to the network. Networks use standardized protocols to ensure that the sending and receiving systems "speak the same language." An internet protocol (IP) address is a numerical label assigned to each computer connected to a standard network. Routers use these IP addresses to ensure that network traffic is delivered to the appropriate recipient.

A local area network (LAN) is a network that connects computers over a small geographic region. LANs are typically managed by a single person or organization. A related concept is an intranet, which is a private network created for use only by members of an organization. A wide area network (WAN) links computers or LANs across a geographically large area; the internet is an example of a WAN. A firewall is a system that permits or denies certain types of network traffic based on a set of rules, typically to create a security barrier between a trusted internal network and the internet.

Cloud Computing

Cloud computing refers to on-demand access to a shared pool of computer resources available over a network. Typically, cloud applications can be used without active management by the end user. Cloud computing has several potential advantages, including easy access to powerful computing resources with low up-front costs, faster implementation times, and a reduced need for internal information technology support. Potential disadvantages include the loss of direct control over your data, decreased customizability, and increased security risks (6). Many cloud computing providers make extensive use of virtualization, a technology where a single physical server can be partitioned into multiple virtual machines by using software to simulate hardware, operating systems, and storage devices. This approach improves efficiency and reliability and simplifies system administration; it is thus widely used by cloud computing providers.

Healthcare Information Systems

Healthcare information systems are electronic systems that facilitate management of the clinical and business activities of healthcare organizations. An EHR is a type of health information system that serves as an electronic version of a patient's medical chart. The EHR may contain data such as demographics, progress notes, lists of medical problems, medications, past medical history, and laboratory and imaging data. Most EHRs include extensive functionality to support patient care, such as provider order entry, integrated decision support, quality management, and clinical outcome reporting tools (7). Other important healthcare information systems include financial information systems, practice management systems, data analytics systems, inventory management systems, and a wide variety of department-specific systems such as pharmacy information systems, radiology information systems, and laboratory information systems.

An organization's healthcare information systems may consist of a patchwork of "best of breed" products that are interfaced to each other to meet the needs of each department or facility. Alternatively, an organization may employ a multifunctional software suite from a single vendor in which component application modules work together in an integrated fashion. A cornerstone of either arrangement is the master patient index (MPI), which is a listing of historical and current patients receiving medical care in the organization. The MPI is a central building block that feeds patient information to all information systems in the enterprise. Because of this critical central role, the integrity of the MPI is closely protected.

It is common for healthcare organizations to install an interface engine at the center of the information system architecture to manage the flow of data between disparate information systems. A properly functioning interface engine gives organizations the freedom and flexibility to select compatible information systems of their choice from a variety of vendors and link them together to provide systemwide communication.

Each information system in the organization is installed on at least one computer that houses the operating system and application software. For critical applications where downtime is not acceptable, the architecture may include server redundancy, with multiple servers hosting instances of the same application. When a primary server is not

本书版权归John Wiley & Sons Inc.所有

available during downtime, user sessions logged onto that server can be moved, usually quickly and automatically, to a different server so users can continue to work. To protect from severe weather and other disastrous events impacting multiple servers in a particular facility, locating redundant servers physically several miles apart minimizes the likelihood that all servers will be affected during a single event. The impact of heavy concurrent user activity on system resources can also be minimized by distributing users across the redundant servers, in a process called load balancing.

A critical aspect of healthcare information system management is ensuring the security of healthcare data. The Health Insurance Portability and Accountability Act (HIPAA) was first enacted in 1996 and has since been strengthened and expanded by subsequent laws. HIPAA enforces the adoption of measures by healthcare organizations to ensure the confidentiality, integrity, and availability of so-called "protected health information" and imposes monetary or criminal penalties for violations (8).

Security measures include familiar strategies like secure passwords, antivirus software, and anti-phishing training for users, but also extend to ensuring the physical security of servers and workstations, establishing network security with firewalls and encryption, and ensuring that all data are appropriately backed up. For backups, the important information contained on each computer should be copied to a second storage medium on a regular schedule, usually daily. Ideally, additional copies of the backed-up files should also be stored in a remote location. Should a disaster occur at the location where a computer is based, the stored information and application software from that computer can be restored using the local or remote backup data.

Laboratory Information System Fundamentals

LIS Architecture

Hardware. An LIS consists of one or more computers and software that provide the array of services described in this chapter. LIS architecture, i.e., the model of how the various hardware and software components function together, differs between various LISes. Most modern LISes are "client-server" systems, where laboratory data are stored on one or more networked servers that can be accessed by multiple client workstations.

With "thick client" LIS architecture, workstations are personal computers capable of running a wide variety of software applications in addition to the LIS, e.g., email, word processing, spreadsheet, and presentation software. With thick client architecture, the LIS application typically runs on the workstation, while the database management system and laboratory data reside on networked LIS servers. By contrast, with "thin client" architecture, the LIS application runs alongside the database management system on networked LIS servers. User workstations are minimally equipped and may be limited to functionality for display of and interaction with the applications running on the servers. These workstations are less flexible but are generally less expensive. Cloud LIS architecture can be considered a variation on the thin client model. Cloud LIS architecture is also sometimes referred to as the "software as a service" (SaaS) LIS model. With this model, LIS software is maintained by the vendor at a remote location and is provided to the laboratory by a secure connection over the internet. As with other cloud computing tools, cloud LISes often have lower startup and maintenance costs, but the laboratory relies on the vendor to maintain availability of the system and to respond to requests for configuration or customization of the system (2).

Other hardware connected to LIS workstations or servers may include:

- Input devices, e.g., keyboards, pointing devices, touchscreens, barcode readers, scanners, cameras
- Output devices, e.g., computer displays, fax machines, printers for preparation of specimen identification labels, worksheets, and reports
- Laboratory instruments, to permit batched or real-time transfer of patient demographic data, orders, and test results. Instrument connections are mediated by interface software, which is discussed in more detail later in this chapter.
- Middleware servers. In the laboratory context, middleware typically refers to software that acts between instruments and the LIS. Middleware provides a wide variety of specialized or expanded functionality not included in some LISes, e.g., automation, rule-based decision support, reflex test ordering based on results, real-time monitoring of laboratory data including quality control and workload management, and specimen storage and management functionality (9).

Software. A database is at the core of every LIS. Database management functionality within the LIS is responsible for data storage, organization, management, retrieval, and integrity (2). Many LIS databases are relational databases, in which data are modeled in rows and columns across a series of tables. While different LISes may use different types of databases and/or may structure their data very differently, there are aspects of LIS data organization that are consistent across most LISes.

LIS dictionaries are the data structures that determine the rules, formats, entity names, and conventions for information processing. Every LIS has a multitude of such dictionaries, the purpose of which may vary widely. Common

本书版权归John Wiley & Sons Inc.所有

examples include test definition dictionaries, which define test names, departments, container types, reference ranges, and other details about specific tests; person dictionaries, which define laboratory users and their roles; container and specimen dictionaries that define different container and specimen types; facility dictionaries that define different laboratory locations or testing sites; and many others. The LIS routes orders to LIS worklists that define which tests are performed at which testing locations and on which instruments, thereby defining the laboratory's specimen and data flow. Worklists are usually entirely virtual but may be printed if necessary. The LIS uses worklists to manage results from both manual testing and interfaced instruments prior to resulting. LIS dictionaries and worklists tailor the function of the LIS to the individual laboratory, so significant time is spent during LIS implementation to ensure that they are configured properly.

LIS Interfaces

An interface is a connection across which information systems exchange information. Most hospitals and healthcare information technology vendors have adopted Health Level 7 (HL7) data exchange standards. The HL7 specifications establish the appropriate structure and type of data in messages between healthcare information systems (10). Interfaces may be unidirectional, where information travels in one direction only, or bidirectional, where information travels in both directions between connected systems. Each of the interfaces described may generate error logs that should be monitored by information technology personnel. Many of the messages recorded in error logs may be routine and of little consequence. However, critical errors may be found in the same logs, and it is those errors that must be recognized and that warrant immediate resolution (11). The major types of LIS interface are discussed below, along with descriptions of related EHR and LIS functionality.

Admission/discharge/transfer (ADT) interface. The LIS depends on the MPI for the most current information regarding individual patient admissions, discharges, and transfers. Usually, the creation of new MPI records or changes to existing records are sent to the LIS instantaneously via an ADT interface, which carries patient demographic information and information about admission, discharge, and transfer events. Such an interface obviates the need for manual entry of patient demographic data in the LIS and ensures that the information in the LIS is up to date.

Orders interface. Direct entry of laboratory orders into EHRs by patient care personnel, also called computerized provider order entry (CPOE), is the norm in hospitals today and is a central component of the universal strategy to eliminate medical errors (12). The ordering of laboratory tests in the EHR should be simplified using logically organized and readily searchable online test menus that offer easy access to information about testing, e.g., specimen collection and transport requirements, turnaround time for results, and testing costs. It is important for billing and compliance purposes that laboratory test names and requisition forms, whether electronic or paper-based, accurately and completely communicate the testing to be performed. For example, if a test order may result in reflex testing and additional billing, the criteria under which the reflex testing will be performed must be clear and consistent to avoid inappropriate over- or underbilling. It is also helpful to maintain a consistent nomenclature and/or mapping between test names in the LIS and EHR; such consistency can improve communication between laboratory personnel and EHR users. Verification that the content and organization of the laboratory ordering screens in the EHR are easily navigated and understandable is a task ideally handled by a laboratorian working in conjunction with a clinician.

EHR ordering systems often include clinical decision support tools, e.g., to assist in selecting the correct test(s), to identify tests that are particularly costly or that require prior authorization from a third-party payor before ordering is permitted, or to check automatically for redundant test orders. Orders that are potentially medically unnecessary or redundant can be displayed in real time on the ordering provider's workstation. If such capability does not exist in the EHR, such tests may also be identified by the LIS after orders have come across the orders interface. In general, these decision support features are most convenient to use when presented to an ordering clinician at the time of ordering, rather than to laboratory personnel after the order has been placed.

Once laboratory test orders are entered in the EHR, they are sent electronically to the LIS via the orders interface. Specimen container labels, usually barcoded, are generated either by the EHR or by the LIS and are applied to the containers, ideally in the presence of the patient. Some LISes include functionality for positive patient identification (PPID), which reduces the rate of specimen identification errors by actively verifying patient identification at the point of specimen collection and by absolute linking of specimens to that patient throughout the testing process (13). Specimens are transported to the laboratory where they are "received" into the LIS, and then testing is initiated. In some hospitals, if a specimen is not received into the LIS within a defined timeframe, e.g., 72 hours, and an acknowledgment of receipt is not sent back to the EHR, the EHR will cancel the order automatically.

Current Procedural Terminology (CPT) codes provide a uniform nomenclature for coding medical services and are used to track and bill for these services. The 10th revision of the *International Statistical Classification of Diseases and Related Health Problems* (ICD-10) (see https://icd.

本书版权归John Wiley & Sons Inc.所有

who.int/browse10/2019/en, accessed 27 July 2023) is a classification system for diseases, symptoms and signs, and related concepts. Third-party payors typically require that the CPT code(s) for laboratory tests performed on outpatients be accompanied by an ICD-10 code that justifies the medical necessity of the test(s). This practice is intended to discourage indiscriminate or wasteful ordering of laboratory tests. Most outpatient order-entry information systems today offer an optional medical necessity checking module that automatically alerts the ordering clinician when there is not an appropriate match between the CPT and ICD-10 codes. Use of this functionality in outpatient order-entry information systems is recommended.

Results interface. The same EHR application used for placing laboratory test orders is also often used for viewing test results. Thus, installation of an orders interface is usually accompanied by a results interface. Preliminary and final test results should be viewable in the EHR shortly after they are filed in the LIS; test result reports may also be printed on paper or delivered electronically by fax, email, or other means. In addition to use by patient care personnel, the information transmitted from the LIS to the EHR may be used to create analytical reports, e.g., "dashboards" used to monitor utilization of laboratory services.

Prewritten ("canned") or *ad hoc* interpretive comments can be attached to reports by the laboratory to assist clinicians in understanding their significance and in learning which additional tests should be considered for ordering. Prewritten comments are often most effective at improving communication when written in collaboration with ordering clinicians. Many LISes have functionality to attach prewritten comments to reports automatically based on specific results or patient demographic criteria.

It is important to understand that developers and analysts designing and configuring EHR systems may not be familiar with the requirements mandated by the Clinical Laboratory Improvement Amendments (CLIA) of 1988 for the display of laboratory test reports (14). Clinical laboratory personnel are uniquely qualified to ensure that test results are displayed in an accurate, unambiguous, and clinically advantageous manner. Therefore, to ensure that configurations meet both clinical and regulatory standards, it is important that laboratory personnel directly participate in the validation and testing of results interfaces and, ideally, in the design of laboratory results displays.

Instrument interface. Connectivity between instruments and the LIS is critically important for eliminating tedious, resource-intensive, manual entry of information into instrument data management systems and into the LIS, especially with high-volume tests. Manual transcription of laboratory data is a source of preanalytic and postanalytic errors that can lead to avoidable patient harm (15). Some instruments rely on intervening middleware, which can optimize management of results with tools like rules, quality control flagging, and autoverification.

A major standard for communication between laboratory instruments and the LIS was promulgated by the American Society for Testing and Materials (ASTM) in the 1980s. While ASTM protocols are still in use, most analyzers now use HL7 protocols instead for communication with the LIS. The current lack of standardization of connectivity and communications protocols between various analyzers and the LIS necessitates expenditure of much time and money by laboratory users and vendors alike in their efforts to establish reliable communication. For this reason, careful instrument interface validation is a critical step in ensuring reliable connectivity between instrumentation and the LIS.

Billing interface. From a financial perspective, the billing interface between the LIS and the organization's financial information system is crucial (16). Automatic billing for laboratory services typically is triggered by the transmission of billing messages across the interface between the LIS and the organization's financial information system. Laboratory test charges are sent either individually as they are incurred or in batches across the billing interface. Depending on the capabilities of the LIS and the organization's billing system, a decision must sometimes be made by the organization's financial leadership as to whether charges should be levied upon specimen receipt by the laboratory, or upon test resulting. Complex financial algorithms dictated by contracts with third-party payors, accountable care organizations, and managed care providers may be processed by specialized LIS or EHR modules and/or may be handled by a financial information system. Universal requirements for successful laboratory billing are that the test charges must be precise, complete, timely, and convertible into a data format acceptable to the payor.

Reference laboratory interface. Virtually all laboratories send some specimens to reference laboratories for specialized testing not performed on-site. The results of send-out tests often are complicated and accompanied by large blocks of interpretive text. Manual transcription of results into the LIS by clerical employees who are frequently unfamiliar with testing terminology is inefficient and error prone. Interfacing the LIS with information systems at each reference laboratory is attractive to both the originating and reference laboratories because it automates labor-intensive processes and minimizes ordering and resulting data entry errors.

LIS Administration

In most laboratories, the LIS and related systems are administered by an LIS team. The LIS team ideally is composed of

本书版权归John Wiley & Sons Inc.所有

personnel with both laboratory and information technology expertise. Usually, the LIS team takes responsibility for configuring the LIS and related systems to support laboratory operations, including instrument interfaces, LIS and middleware upgrades, laboratory user training and support, new product evaluations, system validations, and many other duties. In many organizations, the LIS team works in close cooperation with the institution's information technology department, which is responsible for infrastructure such as network communications, server management, workstation support, and backups.

LIS validation. Validation is the process of verifying and documenting that a system is functioning as intended, i.e., doing what it is supposed to do in a consistent and reproducible manner. LIS validation is a time-consuming and resource-intensive quality assurance activity. As with other laboratory instruments and processes, the laboratory must ensure that all parts of the LIS and related systems are functioning correctly prior to initial use, after any significant system change, and, in some cases, periodically thereafter. Several regulatory and accrediting agencies such as the College of American Pathologists (CAP), COLA Inc. (formerly the Committee on Office Laboratory Accreditation), the United States Food and Drug Administration (FDA), the Association for the Advancement of Blood and Biotherapies (AABB), and The Joint Commission (TJC, formerly Joint Commission on Accreditation of Healthcare Organizations) have specific requirements for the conduct and documentation of LIS validation (3).

To conduct a successful validation, careful planning is required. Validation starts with creation of a validation plan that includes, for example, a detailed description of what will be tested, a description of how testing will be documented, a list of the users who will conduct and approve each aspect of the validation, and acceptance criteria defining the conditions under which the validation will be approved. Some organizations create detailed test scripts, which are documents that contain a series of specific steps to be performed to ensure that each of the appropriate system conditions has been tested. If any part of a script reveals a system failure, a fix is applied, and the system is retested. Often, test scripts are archived alongside screenshots and other validation reports to provide documentation of the validation process for regulatory purposes. Once the validation plan and test scripts are in place, many additional practical details must be managed to conduct the validation, e.g., the resources and timing of the involved laboratory personnel and coordination between teams managing the different hardware and software systems under validation. Given the labor-intensive nature of the validation process, some laboratories elect to employ third-party companies to conduct validations and/or to aid in creation of test scripts. After the validation is complete, the findings should be formally reviewed by the LIS team and laboratory medical leadership for approval.

When implementing a new LIS or conducting a major modification or upgrade of an existing system, the validation should include all potential specimen types and every orderable procedure in the laboratory compendium impacted by the change. It should extend through all phases of the laboratory process, from order entry to result reporting to billing, and should test every component of the LIS and EHR configured to support these phases, including hardware, software, and system processes, as well as user workflows. For many laboratories, it is important to test both inpatient and outpatient scenarios separately, as different types of patient encounter may require specialized orders that need to be configured separately in the LIS and/or that may have specialized considerations for billing. When validating a minor change to an existing system, e.g., changing the reporting terminology for an existing lab test, only validation of that specific component is typically required. Ideally, any change that includes new functionality or modifications to existing LIS functionality is accompanied by user training; the LIS team ordinarily conducts and documents user training prior to implementation of the change.

Change control. Change control is a process to ensure that changes to a system are introduced in a controlled, documented, and authorized manner. Every laboratory should have a formal process for LIS change control. The process can prevent mistakes, and change control documentation is required by regulatory agencies (17). The process should include clear documentation of the reasoning for each change request, a description of the proposed change, and a formal approval process. Validation of significant changes is required, and, ideally, changes should be vetted in a test system before migration into the main LIS. All changes should be communicated to laboratory personnel, clinical users, and other stakeholders prior to implementation.

Downtime procedures. Planned LIS downtimes can occur for routine maintenance or upgrades. Unplanned LIS downtimes occur for many reasons including physical problems such as hardware failures, interruption of network cabling, or loss of electrical power; software problems such as misconfigurations or bugs; and human errors. Thus, every laboratory should have downtime procedures with instructions for manual recordkeeping when the LIS is not available. These procedures should include provisions for manual ordering and manual creation and delivery of result reports, as well as instructions for retroactive entry of manual results into the LIS once normal operations have resumed.

本书版权归John Wiley & Sons Inc.所有

LIS Selection and Implementation

Selection of a new LIS is a strategic crossroads for any laboratory, given the complexity of the decision and its potential to profoundly affect laboratory operations. Before starting any LIS selection project, it is important to clearly define a project team composed of key stakeholders, e.g., laboratory personnel, pathologists, operations managers, or financial managers, that is led by an experienced project manager and that has the support of the laboratory's medical and administrative leadership. Each stakeholder may have a distinct set of concerns about the project (see Table 21.1), so cooperation and clear communication between stakeholders on the project team are critical. The project team is responsible for defining organizational needs, communicating with other internal stakeholders and with vendors, and delineating project steps, required resources, and timelines (3).

Once formed, the project team should clearly document and prioritize the requirements for the new system by defining the current state and required (or desired) future functionality that the new system should have. Typically, the best way to approach this task is to work directly with users of the current LIS to evaluate existing workflows and to identify functional gaps. In other words, the project team should work with LIS users to answer the questions, "What should the LIS do that it can't do today?" and "What are the bottlenecks in current workflows, and how can they be addressed?" (3). For example, a laboratory that currently tracks critical value notifications using an inefficient paper log might identify "electronic critical value notification worklists and tracking" as a desired feature of a new LIS. The process of determining what gaps exist between current and desired LIS functionality is called a needs assessment. Once the needs of the laboratory have been defined, the next step is to evaluate the LIS options on the market and obtain information from vendors. Sometimes, vendor selection includes a formal request for proposals (RFP), where vendors submit detailed descriptions of their products' capabilities in response to each of the laboratory's stated requirements. Ordinarily, vendors will provide detailed demonstrations of project functionality and will arrange telephone or on-site reference checks so the project team can speak with other customers (18). During this process, the project team should evaluate the culture, strategy, and business outlook of each vendor to ensure they are a good long-term fit for the laboratory. Once the project team has gained a detailed understanding of the advantages and disadvantages of each LIS option and has selected the new system, formal contract negotiation typically occurs. The entire process of selecting a new LIS, starting with the formation of a project team and concluding with the signing of the contract, typically takes many months to complete.

Given their fundamental role in laboratory operations, LISes have historically been standalone "best-of-breed" information systems selected, installed, and managed by the laboratory. However, these days, LISes are often acquired and deployed as part of an integrated suite of hospital applications from a single EHR vendor, e.g., as a module within a hospital's existing EHR software. The integrated approach reduces the laboratory's independence in configuring and managing the LIS, which has the potential to adversely impact laboratory operations. On the other hand, an integrated approach may simplify deployment, reduce implementation and management costs, and eliminate the need to maintain an interface between the LIS and EHR (1).

Implementation of a new LIS is a major project that may take many months to complete. As with LIS selection, LIS implementation should begin with the selection of a project team composed of key stakeholders and led by an experienced project manager. Typically, the LIS vendor provides a

Table 21.1 Example stakeholder concerns during selection of an LIS

Stakeholder	Example concerns
Laboratory management	What major functions and detailed features does the LIS provide? Can the LIS support the required locations, users, instrumentation, and projected workloads of the institution? How easy is the LIS to learn and use? What implementation support and ongoing user support does the vendor provide? What workflow changes will be required with the new LIS?
Financial management	What is the short-term cost of purchasing and implementing the LIS? What is the total cost of ownership of the LIS over several years? What are the current and future business prospects of the LIS vendor?
Information technology management	How compatible is the LIS with other existing systems in the institution? What are the LIS's server hardware and software management and support requirements? What are the LIS's peripheral hardware requirements, e.g., label printers, barcode scanners?
Ordering clinicians	How will the LIS impact laboratory test ordering and resulting?

本书版权归John Wiley & Sons Inc.所有

detailed implementation plan with a timeline and milestones and takes an active role in planning and coordination of the implementation alongside laboratory project team members. The implementation process typically includes detailed planning, system configuration, and testing phases followed by "go-live." Critical implementation tasks include assessment of existing laboratory workflows, configuration of dictionaries, worklists, and other elements of the new LIS, configuration of interfaces, transfer of data from the old LIS into the new system, and extensive validation and testing of every aspect of the new system. Prior to go-live, users must be trained, and standard operating procedures must be updated to describe the functionality of the new system.

The go-live itself must be carefully planned. The project team must determine how to manage the transition period during which both the old and new LISes may be active, and contingency plans with downtime procedures should be in place in case the new system fails. Contingency plans typically include criteria for temporarily pausing the go-live and restoring the function of the old LIS. Go-lives should be timed to avoid overlap with other resource-intensive periods, e.g., EHR upgrades, implantation of new instrumentation, or regulatory inspections. The period immediately after go-live is often fraught with challenges. Despite the best efforts of the project team and vendor, unanticipated problems are common after an LIS go-live, so a temporary increase in downtime and laboratory result turnaround time should be expected (18). Even with high-quality training, there may also be some laboratory staff frustration and time lost to retraining given the unfamiliarity with the new system (19).

It is important to note that each of these implementation tasks requires focused work by laboratory personnel, most of whom will have concurrent responsibilities in the laboratory. Thus, it is critical for laboratory managers to accurately account for the work required for an LIS implementation and to balance it with the work required to operate the laboratory. Practically, vendor implementation timelines are often overly optimistic and should be modified by the project team to fit the reality imposed by local laboratory staffing and other resource constraints.

Specialty Considerations

Microbiology

Laboratory workflows associated with microbiology specimens are arguably more complex than those in any other area of clinical pathology. Microbiology testing is performed on a broad array of specimen types, and samples are frequently divided and subdivided. The LIS must be able to identify and track each of these derivative samples. The LIS should have the ability to store and display working notes about specimens so microbiologists can communicate with one another about pending workups. Importantly, in contrast to most clinical laboratory tests, microbiology processing and reporting are often a multistep process requiring a cascade of preliminary and final results to be released as organisms are presumptively and then definitively identified, and as antimicrobial sensitivities are characterized (20). Further, microbiology laboratories are often called on to provide data to help control infections and antibiotic resistance in hospitals. Laboratories may be asked to create antibiograms, profiles of antimicrobial susceptibility testing results for important microorganisms against batteries of antimicrobial drugs. Many LISes contain functionality to facilitate the generation of these and other important epidemiological profiles and reports. Additionally, many microbiological results are required to be reported to public health authorities (21). This unique complexity puts additional demands on the LIS, in terms both of required functionality and of the complexity of configuration and validation.

Blood Banking

Blood banks operate in a highly regulated environment. TJC, AABB, and CAP each impose accreditation standards on blood use, and the FDA regulates the collection, manufacture, and distribution of blood. Furthermore, unlike most LISes, systems with blood bank functionality are considered "medical devices" by the FDA. Like other medical device manufacturers, blood bank LIS vendors are held to a specific regulatory standard and must obtain FDA clearance prior to marketing their systems (22). The potential clinical consequences of clerical errors and other mistakes in the blood bank can be extremely serious, so careful validation of blood bank LIS functionality is required to ensure that the system performs as intended.

The blood bank LIS must manage several specialized functions. In addition to tracking specialized procedures like blood typing, antibody screens, and pretransfusion compatibility testing, the blood bank LIS must be able to keep record of product modifications, e.g., irradiation, leukocyte reduction, and "aliquoting" of fractional blood doses, and must document blood donor and recipient procedures and results. Most blood bank LISes can print the specialized barcode labels for products required by the FDA. The most prevalent barcode standard for blood banking is called ISBT 128. The ISBT 128 standard contains specific data structures for tracking various blood product characteristics, and aids in transfusion medicine standardization and interoperability between facilities.

An additional feature of most blood bank LISes is an electronic crossmatch, where patients with a previous blood type on file, no history of blood group antibodies, and a negative antibody screen are "crossmatched" by the

本书版权归John Wiley & Sons Inc.所有

computer to a compatible unit in the blood bank inventory. Electronic crossmatching is safe, increases the speed at which blood products can be issued in an emergency, and reduces laboratory workload (23). Blood bank LISes sometimes also include functionality to facilitate and document the investigation of transfusion reactions.

Point-of-Care Testing

Point-of-care (POC) tests are performed in many different clinical care settings, usually outside of the laboratory, and by many different clinical personnel. Many laboratories manage multiple types of POC instruments purchased from different vendors, and the instruments may vary widely in their capabilities and their connectivity. In general, POC test results are immediately available on the instruments to be used for patient care. However, unless the POC test results are also displayed in the EHR, they may not be available to other care providers and/or may not be included in the patient's permanent medical record. Thus, the primary challenge of POC testing from the LIS standpoint is managing how information travels between the various POC devices and the LIS and/or EHR (24).

Some POC platforms, such as fecal occult blood testing cards and noninterfaced glucometers, are entirely manual. Users perform the tests, then visually read and manually enter the results into the LIS or EHR. As with other types of laboratory data, manual entry of POC data is an error-prone process (25), so interfaced POC instruments are usually preferable. Accordingly, some POC devices are sophisticated machines with internal databases and bidirectional interface connectivity. Many of these devices use docking stations or wireless networking capabilities to transmit data to and from each POC device. The devices may be connected directly to the LIS, but often are connected to POC middleware. The middleware permits patient demographic information, orders, results, billing information, and quality control and user data to be managed and then transmitted between the POC systems and the LIS and/or EHR. Additionally, some of the POC middleware options on the market can readily interface with instruments from multiple vendors, greatly decreasing the complexity of the required LIS and EHR interfaces.

Molecular Diagnostics

Over the past 3 decades, the laboratory industry has experienced an explosion in methods for detecting and characterizing nucleic acids, proteins, or other molecules that may indicate disease. Most clinical laboratories now readily perform straightforward molecular tests such as the polymerase chain reaction (PCR) for specific microorganisms. Some of the instruments used to perform these tests are internally complex but are straightforward to use and are interfaceable to LISes. At this end of the spectrum, molecular diagnostics pose no major challenge for LIS administration. However, at the other end of the spectrum, there are highly complex molecular tests like microarrays, fluorescence *in situ* hybridization (FISH), cytogenetics, and next-generation sequencing. Much of the required instrumentation for these tests cannot be readily interfaced to LISes. These types of tests have multistep laboratory workflows, challenging data processing and storage requirements, and unique reporting requirements (26). As with other new technologies, billing codes for molecular pathology tend to evolve quickly and/or lag behind the technology; the pace and complexity of these changes can create challenges for LIS administration (27). Unfortunately, the LIS industry in general has not kept pace with the breakneck speed of molecular diagnostics development, so many of these challenges are not readily met by most general purpose LISes. While many laboratories have created workarounds, some have purchased or built distinct specialized information systems for molecular diagnostics and/or may outsource some parts of the process to third-party vendors.

SUMMARY

Modern laboratories depend on LISes to support their operations and to carry out their patient care objectives (2). The obvious "output" of the LIS is a test result or report, but the LIS coordinates most of the day-to-day activities associated with generating those reports (1). This chapter has provided a basic overview of the LIS, but this text is only a superficial overview of this deep and engaging subject, with profound implications for how laboratories are run and the safety, quality, and usability of the critical healthcare services we provide. The LIS is so fundamental to laboratory operations that every laboratorian should have a basic understanding of how their LIS works and how it fits into their organization's information system landscape. Without such an understanding, the laboratorian risks being marginalized from the larger healthcare mission of providing safe, high-quality, and accessible healthcare. Such a mission cannot succeed without the laboratory, and the laboratory cannot succeed without the LIS.

KEY POINTS

- Modern laboratory information systems (LISes) are fundamental to clinical laboratory operations, directly managing the workflow within the laboratory, handling reporting, and facilitating the day-to-day activities associated with generating test results.
- Most modern LISes are "client-server" systems, where laboratory data are stored on one or more networked servers that can be accessed by multiple client workstations.
- The LIS is one of many types of healthcare information systems.

本书版权归John Wiley & Sons Inc.所有

- A database is at the heart of every LIS. LIS dictionaries define the structures, rules, formats, entity names, and conventions for information processing. LIS worklists define which tests are performed at which testing location or on which instrument.
- Healthcare information systems and laboratory instruments may share information via interfaces, most of which communicate using HL7 standards.
- LIS validation is a critical quality assurance activity that is required by accrediting and regulatory bodies. LIS validation is a complex, labor-intensive activity that requires careful planning.
- Laboratories should have formal LIS change control and downtime procedures in place.
- Some laboratory subspecialities have unique requirements for LISes that require tailored functionality.

GLOSSARY

Note: Definitions for some terms were adapted from Wikipedia (28). Terms are listed using acronyms or abbreviations where in common use.

Acceptance criteria The criteria that a system or component must satisfy to be accepted by a user. In the context of LIS validation, acceptance criteria are the conditions under which the validation will be approved.

Antibiogram A profile of susceptibility testing results for important microorganism(s) against a battery of antimicrobial drugs.

Application software Programs that run on a computer to carry out specific tasks other than the operation of the computer itself.

Bidirectional interface An electronic interface in which information travels in both directions between two connected systems.

Change control A process to ensure that changes to a system are introduced in a controlled, documented, and authorized manner.

Client In the context of computing, a client is hardware or software that accesses a remote service on another computer.

Clinical decision support A technology that provides clinicians, staff, patients, or other individuals with knowledge and information, intelligently filtered and presented at appropriate times, to enhance health and heath care.

Cloud computing On-demand access to a shared pool of computer resources available over a network.

Cloud LIS An LIS in which the software is maintained by the vendor at a remote location and is provided to the laboratory by a secure connection over the internet.

CPOE (computerized provider order entry) Direct entry into the EHR of laboratory and other medical orders by patient care personnel.

CPT (Current Procedural Terminology) A procedural code set developed by the American Medical Association that provides a uniform nomenclature for coding medical services. CPT codes are generally used to track and bill for these services.

CPU (central processing unit) The "brain" of the computer. Carries out the instructions of a computer program by performing calculations and logical operations.

CRM (customer relationship management) The process by which businesses manage relationships and interactions with current and potential customers.

Database An organized collection of data stored and accessed electronically.

Database management system A specialized application that interacts with end users and other applications to capture, manage, and analyze the data in a database.

Device driver Software that provides an interface between the operating system and a hardware device attached to a computer.

Dictionary In the context of LISes, a dictionary is a data table that determines the structure, rules, formats, entity names, and/or conventions for information processing.

EHR (electronic health record) A type of health information system that serves as an electronic version of a patient's medical chart.

Electronic crossmatch A process where patients with a previous blood type on file, no history of blood group antibodies, and a negative antibody screen are "crossmatched" by the computer to a compatible unit in the blood bank inventory.

Error log In the context of electronic interfaces, an error log is a file containing a record of errors in the transmission of messages between electronic systems.

Firewall A system that permits or denies certain types of network traffic based on a set of rules, typically to create a security barrier between a trusted internal network and the internet.

FireWire (IEE1394) One of the interface standards for high-speed communications between electronic devices. Apple's name for the standard is "FireWire," a term in common use.

Go-live In the context of electronic systems, a "go-live" is the point at which a change, feature, or system becomes available for use in production.

HL7 (Health Level 7) In the context of electronic interfaces, HL7 is a set of international standards for transfer of clinical and administrative data between software applications used by healthcare providers.

ICD (International Statistical Classification of Diseases and Related Health Problems) A classification system for diseases, symptoms and signs, and related concepts. ICD codes are typically used by third-party payors to justify the medical necessity of a laboratory test.

Interface A connection across which information systems exchange information.

本书版权归John Wiley & Sons Inc.所有

Interface engine A software program that manages the flow of data between disparate information systems.

Internet The global system of interconnected private, public, business, government, and academic computer networks and devices, linked by a broad array of electronic, wireless, and optical networking technologies.

Intranet A private network created for use only by members of an organization.

IP (internet protocol) address A numerical label assigned to each computer connected to a standard network.

ISBT 128 The most prevalent barcode standard for blood banking; includes specific data structures for tracking blood product characteristics.

LAN (local area network) A network that connects computers over a small geographic region, typically managed by a single person or organization.

Load balancing In the context of computing, load balancing is the process of distributing a set of tasks over a group of computing resources, with the aim of making overall processing more efficient.

Middleware In the laboratory context, middleware refers to software that acts between laboratory instruments and the LIS, typically providing specialized or expanded functionality not included in the LIS.

Motherboard The main circuit board in a computer that connects, powers, and allows communication between the different components.

MPI (master patient index) A listing of historical and current patients receiving medical care in an organization.

Needs assessment In the context of LIS selection, needs assessment is the process of determining what gaps exist between current and desired LIS functionality.

Network In the context of computing, a network is a set of interconnections between computing devices that allows the devices to share information with one another.

NIC (network interface controller) A hardware device used to connect a computer to a network.

Operating system Software that manages and coordinates the function of computer hardware, memory, and other processes, providing a consistent interface between the computer's hardware and the application it runs.

Peripheral devices In the context of computing, a peripheral device is an auxiliary device used to put information into and/or get information out of a computer.

PPID (positive patient identification) A system to actively verify patient identification at the point of specimen collection and by absolute linking of specimens to that patient throughout the testing process.

RAM (random access memory) A type of fast, short-term computer memory commonly used for temporary information storage.

Redundancy In the context of information systems management, redundancy is the intentional duplication of critical components or functions of a computer system, with the goal of increasing overall reliability or performance of the system.

Relational database A type of database that models data in rows and columns across a series of tables.

RFP (request for proposal) A process where vendors submit detailed descriptions of their products' capabilities in response to each of a customer's stated requirements.

ROM (read-only memory) A type of (semi)permanent computer memory commonly used to store instructions for initializing hardware and software during computer startup.

Router In the context of computing, a router is a networking device that forwards data between computer networks.

SaaS (software-as-a-service) A software delivery model where software is maintained by the vendor at a remote location and is provided to the customer by a secure connection over the internet.

Secondary storage device In the context of computing, a secondary storage device is a storage device or media that is not always directly accessible by a computer.

Server In the context of computing, a server is hardware or software that provides functionality for other programs or devices.

System software Programs required for the functioning of a computer itself.

Test script In the context of LIS validation, a test script is a document that contains a series of specific steps to be performed to ensure that each of the appropriate system conditions has been tested.

Thick client architecture A client-server configuration where workstations are personal computers capable of running a wide variety of software applications independent of the server.

Thin client architecture A client-server configuration where workstations are minimally equipped and are typically limited to functionality for display of and interaction with the applications running on the server.

Unidirectional interface An electronic interface in which information travels in only one direction between two connected systems.

USB (Universal Serial Bus) One of the interface standards for high-speed communications between electronic devices.

Utility software Programs run by users to configure or maintain a computer.

Validation plan In the context of LIS validation, a validation plan is a detailed description of how a new system, feature, or change will be tested.

Virtualization A technology where a single physical server can be partitioned into multiple "virtual machines" by using software to simulate hardware, operating systems, and storage devices.

本书版权归John Wiley & Sons Inc.所有

WAN (wide area network) A network that links computers over a geographically large area.

Worklist In the context of LISes, a worklist is a grouping of tests to be performed at a specific testing location and on a specific instrument.

Workstation A workstation is a computer, typically in a desktop form factor, designed to be used by a single end user at a time.

ACKNOWLEDGMENTS

The authors would like to acknowledge the contributions of Joseph M. Campos, author of the previous version of this chapter. We would also like to acknowledge Michael Quinton, LaPortia Smith, and Raven Steward for their constructive review and useful suggestions.

REFERENCES

1. **Sinard JH, Castellani WJ, Wilkerson ML, Henricks WH**. 2015. Stand-alone laboratory information systems versus laboratory modules incorporated in the electronic health record. *Arch Pathol Lab Med* **139**:311–318.

2. **Henricks WH**. 2015. Laboratory information systems. *Surg Pathol Clin* **8**:101–108.

3. **Pantanowitz L, Tuthill JM, Balis UJ**. 2012. *Pathology Informatics: Theory & Practice*. American Society for Clinical Pathology Press, Chicago, IL.

4. **Harrison JP, McDowell GM**. 2008. The role of laboratory information systems in healthcare quality improvement. *Int J Health Care Qual Assur* **21**:679–691.

5. **Samuel L, Novak-Weekley S**. 2014. The role of the clinical laboratory in the future of health care: Lean microbiology. *J Clin Microbiol* **52**:1812–1817.

6. **Carter AB**. 2019. Considerations for genomic data privacy and security when working in the cloud. *J Mol Diagn* **21**:542–552.

7. **Centers for Medicare & Medicaid Services**. 2023. Electronic health records. https://www.cms.gov/Medicare/E-Health/EHealthRecords. Accessed 23 August 2022.

8. **Federal Register**. 2013. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; other modifications to the HIPAA rules. https://www.federalregister.gov/documents/2013/01/25/2013-01073/modifications-to-the-hipaa-privacy-security-enforcement-and-breach-notification-rules-under-the. Accessed 8 October 2022.

9. **Riben M**. 2015. Laboratory automation and middleware. *Surg Pathol Clin* **8**:175–186.

10. **HL7 International**. 2023. Introduction to HL7 standards. https://www.hl7.org/implement/standards/index.cfm?ref=nav. Accessed 20 August 2022.

11. **Department of Veterans Affairs OIG**. 2022. The new electronic health record's unknown queue caused multiple events of patient harm. Oversight.gov. https://www.oversight.gov/report/VA/New-Electronic-Health-Record%E2%80%99s-Unknown-Queue-Caused-Multiple-Events-Patient-Harm. Accessed 24 August 2022.

12. **Rubinstein M, Hirsch R, Bandyopadhyay K, Madison B, Taylor T, Ranne A, Linville M, Donaldson K, Lacbawan F, Cornish N**. 2018. Effectiveness of practices to support appropriate laboratory test utilization: a laboratory medicine best practices systematic review and meta-analysis. *Am J Clin Pathol* **149**:197–221.

13. **Morrison AP, Tanasijevic MJ, Goonan EM, Lobo MM, Bates MM, Lipsitz SR, Bates DW, Melanson SEF**. 2010. Reduction in specimen labeling errors after implementation of a positive patient identification system in phlebotomy. *Am J Clin Pathol* **133**:870–877.

14. **Code of Federal Regulations**. 2023. 42 CFR 493.1291 Standard: Test report. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/subject-group-ECFR9482366886d579f/section-493.1291. Accessed 16 August 2022.

15. **Fleishhacker ZJ, Rastogi P, Davis SR, Aman DR, Morris CS, Dyson RL, Krasowski MD**. 2022. Impact of interfacing near point of care clinical chemistry and hematology analyzers at urgent care clinics at an academic health system. *J Pathol Inform* **13**:100006.

16. **Workman RD, Lewis MJ, Hill BT**. 2000. Enhancing the financial performance of a health system laboratory network using an information system. *Am J Clin Pathol* **114**:9–15.

17. **Lorenzi NM, Riley RT**. 2000. Managing change: an overview. *J Am Med Inform Assoc* **7**:116–124.

18. **Kaplan KJ, Rao LKF**. 2015. Selection and implementation of new information systems. *Surg Pathol Clin* **8**:239–253.

19. **Harmening DM**. 2013. *Laboratory Management: Principles and Processes*, 3rd ed. DH Pub & Consulting, St. Petersburg, FL.

20. **Rhoads DD, Sintchenko V, Rauch CA, Pantanowitz L**. 2014. Clinical microbiology informatics. *Clin Microbiol Rev* **27**:1025–1047.

21. **Roush S, Birkhead G, Koo D, Cobb A, Fleming D**. 1999. Mandatory reporting of diseases and conditions by health care professionals and laboratories. *JAMA* **282**:164–170.

22. **Sharma G, Parwani AV, Raval JS, Triulzi DJ, Benjamin RJ, Pantanowitz L**. 2011. Contemporary issues in transfusion medicine informatics. *J Pathol Inform* **2**:3.

23. **Butch SH, Judd WJ, Steiner EA, Stoe M, Oberman HA**. 1994. Electronic verification of donor-recipient compatibility: the computer crossmatch. *Transfusion* **34**:105–109.

24. **Kim JY, Lewandrowski K**. 2009. Point-of-care testing informatics. *Clin Lab Med* **29**:449–461.

25. **Mays JA, Mathias PC**. 2019. Measuring the rate of manual transcription error in outpatient point-of-care testing. *J Am Med Inform Assoc* **26**:269–272.

26. **Roy S**. 2015. Molecular pathology informatics. *Surg Pathol Clin* **8**:187–194.

27. **Sireci AN, Patel JL, Joseph L, Hiemenz MC, Rosca OC, Caughron SK, Thibault-Sennett SA, Burke TL, Aisner DL**. 2020. Molecular pathology economics 101: an overview of molecular diagnostics coding, coverage, and reimbursement: a report of the Association for Molecular Pathology. *J Mol Diagn* **22**:975–993.

28. **Wikipedia, The Free Encyclopedia**. 2022. https://en.wikipedia.org/w/index.php?title=Main_Page&oldid=1114291180. Accessed 7 October 2022.

本书版权归John Wiley & Sons Inc.所有

22

Introduction

Organizational Management of POCT
Administrative Considerations • Setting Goals for POCT Management • Laboratory Certification and Accreditation • Developing Management Structures for POCT

Operational Management of POCT
Determining the Scope of POCT Services • Weighing POCT versus Alternatives • Analyzing Costs of POCT • Assessing the Benefits of POCT Services • Quality Management of a POCT Program

Technological Management of POCT
POCT Innovation • Pandemics, Mass Casualties, and Humanitarian Emergencies Driving POCT Innovation • New Monitoring Technologies

SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENTS
REFERENCES

Management of Point-of-Care Testing

Laura Smy, Kristine Apfeld, Sarah Ampomah, and Molly Thieme

OBJECTIVES

To present the various organizational and operational considerations to effectively implement and manage a point-of-care testing (POCT) program

To describe cost factors in POCT and approaches for analysis of the costs of testing

To provide direction regarding quality management for a POCT program to ensure the quality of testing

To understand the clinical benefit of POCT

To appreciate what drives POCT innovation and ongoing technological advances and how these changes impact POCT

There will be obstacles. There will be doubters. There will be mistakes. But with hard work, there are no limits.

Michael Phelps

Point-of-care testing (POCT) presents some management considerations (Table 22.1). Many challenges presented by POCT are different from those of centralized laboratory testing. Common challenges to be managed include crossing traditional physical and organizational boundaries, performing tests at many locations, training a large number and variety of personnel with limited laboratory experience, capturing test results and control values into information systems, blending test results with central laboratory results in the electronic health record, standardizing processes in large health systems, and difficulty in tracking costs and program activity. In many respects, POCT requires management "outside the box," not only the physical box of laboratory space, but also the usual boxes of organizational structures, groups of coworkers, testing devices and technologies, laboratory practice, and management information systems. In this chapter, POCT management is categorized into organizational, operational, and technological considerations, although some of the items listed overlap into more than one category.

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch22.

本书版权归John Wiley & Sons Inc.所有

Table 22.1 Management considerations for POCT

Organizational	Residual historical resistance of laboratories to POCT Competition between POCT and central laboratories Setting goals Cooperation across multiple departments Deciding who controls/directs testing Developing a management structure Assignment of costs and revenue Management across varying lines of authority Deciding about certification and accreditation of POCT
Operational	Determining the scope of POCT services Weighing alternatives to POCT Analysis of costs Standardization of POCT across many sites Training many, diverse staff to perform POCT Experience and training of testing personnel Documentation of test results: centralized, data management Ensuring personnel safety Quality management program Potential lack of equivalence of POCT versus central laboratories Inventory management Management of information Billing
Technological	Growing menu of tests that can be performed as POCT Rapid change in POCT devices Rapid changes in testing technology New monitoring technologies

There is not complete agreement about the definition of POCT, and a variety of other terms such as "near-patient," "bedside," or "alternative-site" testing are used as approximate synonyms. For laboratory inspections, the College of American Pathologists (CAP) defines POCT as tests that are "used at or near the site where the patient is located, that do not require dedicated space, and that are performed outside the physical facilities of the clinical lab" (1). However, many of the management considerations discussed in this chapter also apply to what CAP calls limited-service satellite laboratories, e.g., small laboratories in micro-hospitals or emergency departments, if they are also staffed by non-laboratory healthcare professionals and use instruments typically meant for POCT.

POCT is one of the most rapidly growing and changing segments of laboratory testing. Market analysis reported the POCT market accounted for US$34.6 billion in 2021 and has a projected growth rate of 7.9% from 2022 to 2030 (2). Glucose testing is the most widespread component of POCT, but a significant driver of the growth was the SARS-CoV-2 2019 (COVID-19) pandemic (2). POCT devices are continuing to evolve rapidly, and technological advances have made it possible to perform a wide variety and increasing number of laboratory tests as POCT. This chapter concentrates on the management considerations that will contribute to a successful POCT program.

Organizational Management of POCT

Administrative Considerations

Up until the mid-1990s, many laboratory professionals were highly antagonistic to the perceived competition and lower analytical quality provided by POCT. During its inception, laboratory leadership either embraced POCT or distanced themselves from it. The latter group of leaders secured the four walls of the laboratory and did not facilitate the creation of a strong POCT program for those outside the walls of the laboratory. Non-laboratorians were left without the necessary guidance and training to achieve POCT excellence. Inappropriate test methods were chosen with poor test performance or limited clinical need to reduce turnaround times, and it was challenging to develop a lean and standardized POCT program. Despite this bumpy beginning, POCT continued to grow as testing technologies advanced, and, over time, resistant laboratories came onboard to support POCT. The growth of the Point-of-Care Testing Coordinator role is indicative of laboratory executives recognizing that laboratory oversight and support of POCT are key to a quality POCT program. Additionally, a good POCT program creates a connection between laboratory professionals and other healthcare professionals in the institution that may not have formed otherwise.

Input from laboratory professionals in POCT is essential in promoting the quality of testing, based on long-standing problems recognized for POCT (3) and on studies of testing in physician office laboratories (4). Some of the reported problems include failure to perform quality control (QC) testing, improper testing technique leading to inaccurate test results, and inadequate staff training and competency assessments. Despite increased recognition of the importance of teamwork, healthcare organizations are complex political environments. Each department or patient care unit performing POCT will have its own experience, expectations, and sense of ownership of the POCT performed within its domain. Acceptance of centralized management of POCT requires a commitment from central administration and leaders of testing departments and the perception of non-laboratorians that there is an overall benefit in having the laboratory supporting the POCT team.

On a federal level, POCT has a history of being polarizing. Rapid human immunodeficiency virus (HIV) tests, determined to be waived according to the Clinical Laboratory Improvement Amendments (CLIA), were available in 2002, but it was not until July 2012 that they were approved as over-the-counter home-use tests. Principal arguments against selling over-the-counter HIV POCT were that patients would not have immediate access to proper medical counseling upon receiving the results.

本书版权归John Wiley & Sons Inc.所有

There were also concerns that allowing untrained users to perform these tests would result in a high percentage of false results. In the end, the benefit of increasing access to HIV testing outweighed the risks. Additionally, during the COVID-19 pandemic, the Food and Drug Administration granted Emergency Use Authorization to home-use COVID tests, to encourage people to perform testing and to self-isolate if the test was positive to reduce the spread of the virus. These home tests are not under the management of the POCT program or laboratory. However, questions arise of how to properly document the results of tests performed at home in the electronic health record (EHR). Consideration must be made to differentiate home-use test results from laboratory or POCT test results in the EHR and to ensure that they are documented with the same level of accuracy.

Setting Goals for POCT Management

Beyond the laboratory embracing POCT, one of the key initial steps in the management of POCT is the development of institutional goals. Common motivations for hospital administration and patient care units to seek additional management support for POCT are deficiencies in accreditation surveys, difficulty in meeting or understanding accreditation standards, and problems with the quality of POCT results, resulting in complaints or lawsuits and requests for assistance to address laboratory regulations. In response to these acute problems, plans to revamp POCT management structure often are made retroactively, in a crisis mode. Success is viewed narrowly as passing the next inspection or solving the acute problem. However, deciding that the primary goal in managing POCT is to address regulatory requirements is a limited vision that may lead to overlooking opportunities for improving the quality and efficiency of patient care or potential clinical benefits of POCT. Developing a broader vision of the goals of POCT and a commitment from institutional leadership, including laboratory leadership, generates a positive sense of mission and purpose. More extensive goals in management of POCT are to provide testing that will improve patient care and to improve organizational efficiency (Table 22.2). Meeting regulatory requirements is also a necessary goal, but regulations may be of greater value as a means than as an end. Regulations and inspectors provide guidance, incentives, and useful tools for maintaining the quality of testing and meeting more ambitious goals.

Table 22.2 Goals of POCT program management

Improve the quality of patient care
Enhance the efficiency of and access to patient care
Increase clinician and healthcare staff satisfaction
Improve patient education and satisfaction
Fulfill federal and state laboratory regulations
Decrease liability risk
Address accreditation standards, if applicable

Laboratory Certification and Accreditation

Decisions about how POCT will be certified, and possibly accredited, influence how POCT will be managed and the types of tests that can be performed. Federal CLIA certification is required for all entities performing clinical laboratory testing in the United States (5). CLIA regulations describe specific standards and personnel requirements and qualifications for three levels of testing complexity—high, moderate, and waived. If all testing falls in the waived category, laboratory testing can be performed under a certificate of waiver, which has less stringent requirements than other levels of testing. For nonwaived testing, which encompasses moderate- or high-complexity testing, there are a few certification options, such as a certificate of provider-performed microscopy, a certificate of compliance, or a certificate of accreditation that will also cover waived testing. A certificate of accreditation allows several agencies, including the CAP, the Joint Commission (TJC), and COLA Inc. (formerly Commission on Laboratory Accreditation), to have the authority to accredit laboratories. Some states also have specific regulations that must be met. When nonwaived, moderate-complexity testing is going to be offered in a POCT program, the laboratory director should consider and confirm in advance whether the testing personnel satisfy the more stringent education and experience CLIA requires.

The initial question to address is how many and what types of certificates are needed. It is possible to perform POCT under the same certificate as the central laboratory. However, laboratory directors may be reluctant to cover POCT under their certificate due to concerns about compliance of POCT with laboratory standards and lack of direct control over test performance. Also, including POCT under the main laboratory certificate means that, if applicable, the same accreditation standards are applied to POCT and central laboratory testing. Some POCT programs, particularly those including only waived testing, decide to apply for a separate certificate of waiver for POCT, to simplify requirements. Although CAP may inspect the central laboratory, if POCT is under a different CLIA certificate, it may be inspected by a different accrediting agency that has fewer regulations for waived testing. POCT can be performed under one certificate for multiple locations within a facility if they are contiguous, which often occurs for the sake of efficiency for director coverage and the application process and to avoid additional fees. Further, there are certain exceptions that will allow multiple, noncontiguous testing sites to be included on one certificate, for example, temporary testing sites or mobile units (6).

本书版权归John Wiley & Sons Inc.所有

Developing Management Structures for POCT

In developing the management structure for POCT, central administration and departmental leaders need to collaborate to make key operational decisions. These include determining institutional priorities for POCT, identifying the laboratory's role in the POCT program, selecting a (CLIA) director for regulatory oversight, deciding on a test menu based on clinical need, cost, and test method performance, and determining cost and revenue allocation. A multidisciplinary oversight committee can serve to guide these decisions and to assess evolving needs for POCT, providing valuable bidirectional communication with participants in POCT. Considering the diverse range of stakeholders in POCT, it may be useful to have representation of POCT testing personnel, healthcare providers, laboratory and hospital administrators, information technology (IT) specialists, and laboratory directors and technologists. Such a committee can advise about needs for general changes in policy, weigh in on compliance issues, review quality metrics, and oversee requests for changes in the test menu or sites of POCT.

Day-to-day operations may typically be overseen by POCT coordinators, with consultation support provided by the laboratory director when needed. However, there is much greater variation in organizational structure than there is in other areas of the laboratory. The most common organizational structure is nurses or other non-laboratory staff performing testing organized under a single POCT management. Problems inherent in the centralized management of a widespread POCT program are difficulty in training and assessing competency of the testing personnel, maintaining effective communication with all units and staff, cultivating accountability, implementing consistent practices at all testing locations, and managing numerous staff across varying lines of management authority. Due to competition between POCT and other patient care duties on the patient care units, it is important to identify POCT skills as required core competencies and elements of job performance for the testing personnel and to have active participation of their leadership in corrective action when issues arise. A supportive health system education department is an asset. POCT program managers need to use strong communication skills to build relationships with key hospital leaders to reduce the risk of needing to resort to drastic actions, such as withdrawal of testing devices or authorization for testing, to create the necessary urgency for correcting problems.

A second organizational model is for each clinical department or patient care unit to manage its own POCT. This simplifies the management of each unit; however, it has likely become less common due to the desire for laboratory oversight of POCT, the challenges of standardizing procedures and equipment, and difficulty coordinating testing activities within an institution. This organizational model may apply more frequently when laboratories do not embrace POCT or when a specific type, or types, of POCT is limited to a single unit or at a remote location.

Operational Management of POCT

Determining the Scope of POCT Services

One of the most critical operational challenges is deciding what sites will perform POCT and what test menu should be offered. A starting point for this analysis is to inventory the types of tests and testing volumes of ongoing POCT. Obtaining an accurate inventory of POCT can be difficult due to the dispersed nature of testing, the lack of information systems, and, in some cases, the lack of recognition of what represents a laboratory test. Commonly overlooked POCT activities might include occult blood testing, urine dipstick testing, physician-performed microscopy, and whole blood coagulation testing. Many POCT devices are small, portable, and distributed among many sites, so it can be difficult to find or count the devices. Surveys of patient care units often provide incomplete responses. It may be necessary to resort to information from vendors, EHR test volume reports, purchasing departments, or material management departments to determine the number of analyzers and the volume of testing.

The major source of demand for POCT has been from clinicians who want rapid laboratory results for clinical decision making. A large gap exists between the expectations of clinicians and laboratory targets for turnaround times (7). Surveys of clinicians indicate that they believe that STAT test results for analytes such as electrolytes and glucose should be available within about 15 minutes, while laboratory professionals often have set the STAT turnaround time goals as 60 minutes or less (7). This gap between clinical expectations and laboratory service delivery has led to the high demand for POCT. Further, vendors' sales representatives may connect with providers directly, sparking providers' desire to use the latest POCT device or test technology available.

Turnaround time usually is perceived as the key advantage of POCT, but there are several other factors that may come into play for specific tests or clinical situations (Table 22.3). Use of a smaller specimen volume for POCT and the frequent ability to test fingerstick specimens versus blood draws may be an important consideration for care of infants, young children, and difficult-draw patients. Lower capital costs of POCT for equipment or facilities may be important advantages for infrequently performed tests. For some tests, such as whole blood coagulation tests, specimens collected without anticoagulant must be tested immediately; these tests are most appropriate for POCT. For the care of patients with diabetes, POCT of blood

本书版权归John Wiley & Sons Inc.所有

Table 22.3 Advantages and disadvantages of POCT versus central laboratory testing

Advantages	Disadvantages
Faster turnaround time	Lower accuracy and precision
Smaller specimen volume	Less-skilled testing personnel
Lower capital cost	Higher supply costs
Immediate access to results	Possible lack of comparability with laboratory results
Patient education and satisfaction	Added IT complexity and cost of connecting to data systems
Clinician satisfaction	Difficulty in ensuring quality
Improves access to healthcare	Difficulty in managing testing

glucose and hemoglobin A1c can be viewed to have educational value and to address patient expectations. POCT for coagulation and diabetes-related tests are excellent examples of POCT that can allow for clinicians to adjust treatment during an appointment instead of following up with the patient after results from the central laboratory are reported.

Some common disadvantages of POCT that must be weighed are possibly lower accuracy and precision of tests, less laboratory experience of staff performing tests, and potential lack of comparability with central laboratory results, as well as the difficulties of managing POCT, ensuring quality, and capturing test results into central information systems. However, efforts to specifically address these elements can be incorporated into a POCT program to lessen their potential negative impact.

One point that may be overlooked in considering where to perform POCT is whether to offer the test at all. There must be a clear clinical justification for any POCT that is performed, as well as an assessment of whether increasing the speed of testing will result in significant improvement in the quality or efficiency of patient care. Further discussion of POCT clinical benefits is provided later in this chapter.

Weighing POCT versus Alternatives

Usually, POCT is not the only option for performing a test. Common choices for delivering a test include performing it in a central laboratory, in a satellite laboratory, or as POCT. The first option, and in many cases the most efficient and cost-effective, may be to improve central laboratory processes to meet turnaround time goals. This might involve changes in infrastructure such as installation of a pneumatic tube system for rapid specimen delivery, implementation of automated or robotic lines within the laboratory, changes in laboratory instrumentation to perform analyses on whole blood rather than serum or plasma, and implementing mechanisms for automatic reporting of test results such as autoverification (8). When tests are designed for POCT use, such as qualitative drugs of abuse tests, a lipid panel test, or whole blood cardiac marker tests, the assumption may be made that the tests should be performed as POCT based on history within an organization or the availability of a POCT test. However, the advantages and disadvantages of performing the test as POCT should be contemplated, considering the factors listed in Table 22.3. If the specimens are stable, it may be desirable to perform these tests in the central laboratory even though the test device is acceptable for POCT use. For some tests such as those for drugs of abuse, there may be special considerations such as complicated legal issues and a need to confirm positive results, and this issue must be considered in evaluating whether it is desirable to perform POCT (9). Additionally, a potential barrier to performing group A *Streptococcus* (*Streptococcus pyogenes*) POCT outside the laboratory may be the need to reflexively confirm negative results with bacterial culture or a molecular confirmatory method.

Setting up or maintaining a satellite laboratory represents a major commitment and expense for facilities, equipment, and laboratory staff. Usually, this commitment of resources is justified only when there is an acute clinical need for rapid turnaround time, a high volume of testing, and use of relatively complex testing procedures.

A final factor for consideration with respect to POCT versus alternatives is the safety of testing personnel. When deciding whether to offer or continue POCT, the safety of the testing personnel and all others working within that area must be protected by ensuring that the proper protective equipment is available for use and used by the testing personnel. For example, performance of POCT for COVID-19 and/or other respiratory diseases, such as influenza or respiratory syncytial virus, during the COVID-19 pandemic may not have been offered or may have ceased, opting to send all testing to the central laboratory. The POCT program management may decide to proceed this way due to an inability to uphold recommended cleaning practices or provide recommended supplementary protective equipment against respiratory aerosol production and exposure during testing. Depending on the stage of a pandemic or virulence of the infectious agent, the recommended protective equipment when manipulating samples for POCT may be to use any or all of an N95 mask, goggles or face shield, gown, gloves, and a splash guard or biological safety cabinet (10), which may be difficult to provide at some POCT sites.

Analyzing Costs of POCT

Although it would seem that the cost of a test would be an objective quantity that could be calculated precisely, the absolute and relative costs of POCT and central laboratory testing are some of the most debatable issues relating to POCT. Older publications concluded that POCT is more expensive than the same test performed in a central laboratory (11, 12). One report went so far as to conclude,

本书版权归John Wiley & Sons Inc.所有

"The costs of central laboratory testing are always very much less than that of distributed testing" (12). However, it is notable that the major cost identified for POCT in those publications is for labor. Accounting for labor for POCT is difficult because it involves small bits of time by many staff. There is a paradox in that if you add up all the time spent collectively performing POCT, it represents a substantial number of hours that may equal the time of several full-time equivalent (FTE) staff members. However, POCT programs are not usually designed to have dedicated FTE staff performing the tests. Instead, POCT is typically one of multiple job functions for the testing personnel. Often the only recognized and budgeted impact on FTE staff is for one or more positions as POCT coordinator.

POCT and impact on FTE staff. There are several possible reasons why performing POCT in a patient care unit may have minimal direct impact on FTE staff. A time-and-motion study of nurses, comparing time spent to perform a POCT glucose test versus time spent to draw a specimen for central laboratory testing, noted that less time was required by nurses to perform a glucose test than to collect a specimen and send it to the laboratory (8). The entire glucose POCT process from specimen collection and testing to result retrieval was completed in one brief episode, about the length of time required to draw blood. Sending a sample to the laboratory required multiple steps at different locations spread over about 1 hour—generating a test requisition and label, performing phlebotomy, transporting the specimen to the nursing station, and retrieval of results from the computer. The timing study points out that there may be an underaccounting of the labor required to send specimens to the central laboratory and retrieve results, and that there is the potential for POCT to save labor even without accounting for the labor to perform the test within the laboratory. In addition to the greater amount of time directly spent by patient care staff to send the sample to the laboratory, the delay between testing and receipt of results may lead to indirect inefficiencies and less effective patient care because adjustments of diet and medication wait on receipt of test results.

Cost analysis complications. There are a few complicating factors that affect cost analysis. First, two fundamentally different approaches are applied—a bottom-up, or microcost, analysis that adds up individual cost elements of a test, and a top-down, or macrocost, analysis that determines cost per test based on overall department budgeted costs. Second is the problem of allocation of overhead or small bits of labor that do not result in changes of FTEs, such as patient care staff time spent on POCT. Third, most analyses of labor costs do not account for changes in productivity. For example, if staff perform an additional task without an increase in worked hours, it represents a change in productivity, not a labor cost. Finally, the most important complicating factor is weighing the indirect effects of POCT on the overall cost of patient care (13). Laboratory tests account for a small proportion, perhaps 5%, of healthcare costs (14). If changes in laboratory testing have any impact on factors such as length of stay or changes in clinical outcome, the cost impact potentially could be far greater than the total amount spent on laboratory testing.

A 2003 study demonstrated how POCT can affect treatment decisions in a substantial proportion of testing episodes, although the net effect on costs was not clear (15). Other interesting examples have been described in which POCT may result in substantial savings by having impacts on processes such as frequency of transfusion (16) or in which rapid intraoperative parathyroid hormone (PTH) testing contributes to an overall cost reduction. Although providing intraoperative PTH testing can cause an increase in laboratory costs, total costs for patient care appear to be decreased substantially by decreasing surgical time and/or making the procedure more efficient and effective (17, 18). Improvements in the quality and the efficiency of patient care delivery or reduction in transfusion frequency have been considered to result from POCT in several other cases, with the potential for overall cost reduction (19, 20).

However, difficulty in arriving at an exact dollar benefit for a change in clinical process or outcome makes these analyses challenging and likely not generalizable (21). Published analyses of the costs of POCT tend to be cohort-specific, and in many cases, the value of POCT may not be realized due to the lack of study (21). Differences in approaches of cost analysis and lack of recognition that there is more than one way to calculate the cost of a test lead to much of the variability about the economics of POCT. For most purposes, representing the costs of POCT by an analysis of budgetary impact performed by a macrocost analysis of labor (measured as FTEs) rather than by a microcost analysis of labor (measured as minutes performing tests) may be better because changes in FTEs account for changes in productivity and efficiency.

Other differences in the economics of POCT. Besides the labor component, there are other ways in which the economics of POCT generally differ from those of central laboratory testing. Usually, the supply costs are higher for POCT and a higher proportion of tests are used for quality assurance purposes because a much larger number of devices and testing personnel need to be assessed. While POCT QC and device maintenance is often minimal, it should be completed by those performing the patient testing and at defined intervals regardless of testing volumes. The high proportion of tests used for QC and fixed requirements for performing maintenance as

本书版权归John Wiley & Sons Inc.所有

required by the manufacturer lead to substantial economies of scale for performing a higher volume of testing (11). Performing POCT at sites with low testing volumes leads to higher supply, equipment, and labor costs per test. Due to wide variation in the costs of different POCT, the testing volume threshold that defines a significant economy of scale will vary. Each situation must be analyzed with respect to the direct cost factors, the clinical necessity for rapid turnaround time, and other impacts to patient care.

Additional potential problem areas in the economics of POCT are in management of reagent wastage, utilization of testing, and duplication of POCT and central laboratory testing. These problems may lead to higher-than-expected costs for POCT. Checking a small proportion of POCT results with the same test performed in a central laboratory may serve as a useful quality assurance process (22). However, if POCT is often repeated with a duplicate test in the laboratory, this will have a major impact on the analysis of costs and may represent an issue with the performance of the POCT device, test-ordering patterns, or confidence in the clinical reliability of the POCT. Keys to managing these sources of increased costs are selection of high-performing devices, good systems for inventory management, data systems that allow review of test utilization patterns, understanding billing and reimbursement protocols, agreement with and among clinicians regarding appropriate test ordering practices, and effective training of staff.

Finally, more and more POCT device manufacturers and third parties are offering software options, referred to as data management systems, middleware, or computer interfaces. These computer programs or services offer the ability to monitor devices and manage device settings from afar, connect devices to the laboratory information system (LIS) and/or EHR, and offer tools for testing personnel certification and competency assessment, which are highly advantageous to POCT program management but sometimes require additional expense. The costs include the financial expense to purchase or lease software or access internet-based programs, as well as the personnel costs for expertise to implement, validate, and maintain the system, and the cost of obtaining and maintaining an adequate telecommunication infrastructure.

Assessing the Benefits of POCT Services

Clinical impact. An important part of deciding whether a point-of-care test should be adopted is assessing its potential clinical impact. The general assumption is that faster results make for better patient care and better outcomes. However, POCT may not always offer optimal results if proper protocols and techniques are not followed and QC is not performed. Even if the testing is conducted properly, the accuracy and precision of POCT may be poorer than those of laboratory-based methods due to differences in assay method or instrumentation. A performance trade-off in favor of a more rapid turnaround time may be acceptable, but it is important that the risk of possibly lower performance be weighed carefully against the benefit of a faster result. Quantifying the benefit of POCT can be difficult because important outcomes such as patient satisfaction and employee efficiency do not lend themselves to objective measure. The following are just a few examples of how POCT has been shown to improve a variety of outcomes.

POCT and resource utilization and stewardship. Resource utilization and stewardship are a key consideration when implementing POCT. In some cases, POCT can be used to more efficiently allocate valuable supplies such as blood products. In one prospective randomized trial, POCT was used in cardiac surgery patients with a perioperative coagulopathy to manage hemostatic therapy. In this study, patients were randomly assigned to either conventional hematology and coagulation testing or a POCT group using thromboelastometry and platelet aggregometry. The study found that on average the POCT group required fewer blood products (5 units versus 3 units) (23). These findings have been replicated in other settings and suggest that POCT can have a meaningful impact on the utilization of blood products (24). POCT can play a role in antibiotic stewardship and management of influenza patients as well by reducing the delay in receiving actionable test results. For example, one Irish hospital's experience after implementing influenza A and B POCT resulted in influenza-positive patients receiving 33% fewer doses of antibiotics, an increase in antiviral medication administration, and a decrease in the patient's length of stay from 5.3 to 3.7 nights (25). More on length of stay in the next section.

Length of stay. Length of stay in the emergency department is a common measure used to assess the impact of laboratory testing and can be considered a marker of both resource utilization and quality of care. It seems logical that faster test results would lead to shorter lengths of stay, but if testing provides erroneous results and inappropriate care, lengths of stay may be longer. A variety of POCT can reduce lengths of stay for patients in the emergency department as reported in a 2021 review, but not all studies reported a decreased length of stay, and the reasons why are unclear (26). However, in some cases, clinicians still hesitate to trust POCT for certain tests, sending samples to the laboratory for analysis instead, such as troponin, which makes the impact of POCT on length of stay difficult to assess (27). Although evidence suggesting that POCT has any impact on inpatient length of stay is scarce, it has been shown to reduce the need to admit patients in the first place, which is an equally valuable outcome (28).

本书版权归John Wiley & Sons Inc.所有

Improved Access to Healthcare. Another significant benefit of offering POCT is providing better access to healthcare for patients. This can manifest in several important ways. POCT can be used to provide rapid and discreet results to patients who might not otherwise submit to testing, such as through access to HIV POCT for patient populations who are unlikely to seek healthcare. The goal of offering HIV testing in these settings is not only to make the diagnosis but to link newly diagnosed patients to care. This may seem obvious, but understanding this goal can help guide the management of how HIV POCT is offered. Modeling studies have extrapolated findings to conclude that increased HIV test frequency is a critical component to reducing HIV transmission (29).

Rural settings or developing countries are precisely the environments in which POCT can have the greatest impact by creating access to healthcare. In these settings, patients travel long distances to seek healthcare and are unlikely to make the trip back to follow up on laboratory results that are not immediately available. An example from sub-Saharan Africa suggests that an average of 40% of HIV-positive patients either do not provide a blood sample for testing or do not return for their CD4 count results (30). Another significant challenge in rural settings is transporting specimens to larger laboratories for testing. There are barriers in few personnel being available to courier samples and lack of means for transportation which, when available, comes at a high cost (31). POCT has also been reported to produce financial benefits in these settings through decreased transfers to base hospitals and an increase in patient discharges (32).

The simplicity of POCT also offers advantages in these environments that may have inconsistent power, lighting, and refrigeration, which makes offering conventional laboratory testing difficult, if not impossible. Physicians may grow to distrust conventional laboratory results in these settings and often rely on clinical diagnosis and empiric treatments. However, POCT may offer testing with a better chance of success. High staff turnover can also be problematic in rural and developing settings. The simpler the test, the easier it is to maintain competency and train new technologists. In India, Kabra and Kanugo speculated that training and retaining those skilled staff were the greatest challenge to maintaining a quality POCT program (33). One misconception with POCT is that because it can be simple, it does not require training. In a setting where personnel are unfamiliar with laboratory procedures and practices, quality control and proficiency testing (PT) programs can be difficult to implement because they are time-consuming and expensive. In these resource-limited settings, conveying the importance of performing testing that is not going to contribute directly to patient care and may add significantly to total cost can be tough, although, in their review article (34), Shott and colleagues illustrated how critical it can be to provide quality results and eliminate laboratory error in these settings. Using HIV testing in sub-Saharan Africa as an example, they postulated that with the high volume of HIV testing in this setting, a small error rate of 0.5% could lead to the misdiagnosis or mismanagement of approximately 50,000 patients (34). Rasti et al. discussed the potential for patients to be told they have HIV and be treated with antiretroviral medications based on a false-positive POCT result (35). Although trained laboratory staff would ideally conduct testing, this may not be realistic in these settings.

Further, POCT can enable healthcare systems to provide care to underserved communities and to patients experiencing homelessness or other vulnerable situations. Community-based programs in Los Angeles and New Orleans offered same-day POCT for sexually transmitted infections, which increased the number of high-risk adolescents who received same-day treatment and who also took a treatment pack for their partner (36). The challenges faced by patients who are homeless to attend clinic appointments, or in transporting samples collected on the street to a central laboratory, prompted the Street Medicine group in Los Angeles to implement POCT for essential tests including macroscopic urinalysis, urine pregnancy test, and creatinine, electrolytes, glucose, and hemoglobin in whole blood (37). Importantly, they selected POCT devices that correlated well analytically to the hospital laboratory instrumentation and were already in use in the health system, which provided multiple benefits such as familiarity with the devices and already available procedures, training, and competency materials. As a final example, in patients at risk of hepatitis C infection, such as people who inject drugs, are experiencing homelessness, or have alcohol use or mental health disorders, POCT for active hepatitis C resulted in 83.1% of patients seeking follow-up care and 65.8% completing therapy (38). Two of those patient populations were identified as less likely to complete hepatitis C treatment; thus, POCT helped to identify opportunities for future focused healthcare efforts.

Clinical outcomes. The most important measure of a test's value is the clinical outcome. The wide variety of POCT available makes a comprehensive review of its clinical impact outside the scope of this chapter. The following are a few representative examples to illustrate the clinical impact one can hope to achieve with POCT. (i) POCT, along with an extensive resident education program and team-based approach, resulted in a statistically significant improvement in the number of patients with diabetes who achieved their goal hemoglobin A1c, low-density lipoprotein, and blood pressure levels (39). (ii) Researchers found that offering CD4 POCT significantly improved the chances of initiating patients on antiretroviral therapy for the treatment of HIV

本书版权归John Wiley & Sons Inc.所有

infection (40, 41). (iii) Mortality was significantly lower when POCT for lactate measurement was used to manage pediatric patients following congenital heart disease surgery (42). When compared to conventional testing, the POCT group had statistically lower mortality in neonates (2.4% versus 6.2%, $P < 0.007$) and those patients undergoing the highest-risk surgeries (9% versus 30%, $P = 0.03$).

POCT can have a positive impact on many different aspects of patient care. However, the majority of studies assessing the impact of POCT focus on cost, resource utilization, and emergency department length of stay. More studies are needed to assess the true impact of these tests on clinical outcome (32, 43).

Quality Management of a POCT Program

Reports about patient harm from errors in medical care underscore the importance of developing strategies for achieving quality in POCT (44). Therefore, a POCT quality management program should aim to have the same requirements as found in the central laboratory program, encompassing evaluation of preanalytical, analytical, and postanalytical processes using key performance indicators (KPIs). At a minimum, quality management practices should ensure that appropriate staff training and competency are occurring and that all manufacturers' requirements are met for quality control and maintenance performed. Although the goals of a POCT quality management program are similar to those for the central laboratory, there may be differences in implementation due to the highly distributed nature of testing as well as the number and variety of staff involved.

Preanalytical processes. POCT is prone to the same preanalytical issues as samples sent to a central laboratory, such as incorrect patient identification or specimen labeling, incorrect sample type or tube collected, and poor sample collection technique. Thus, in a POCT setting, it is imperative to train staff regarding the potential preanalytical issues for each test and to arm them with the skills to prevent such issues. Because preanalytical issues will likely still occur, providing the knowledge and skills training for detecting and managing preanalytical issues is also important. This knowledge may actively engage the testing personnel in understanding how the quality of test results they are producing impacts patient care.

When POCT devices are connected via computer interface to the LIS and/or the EHR, the software can be a useful tool for detecting some preanalytical issues such as improper sample collection documentation in the computer, incorrect sample identification for testing, or selection of the incorrect test cartridge for the order placed. When mistakes in workflow such as these occur, the information can be captured by the software and used to provide feedback to the staff, resolve the error, and optimize workflows to reduce issues in the future. However, not all POCT is connected to an LIS or other middleware, and results may be documented as direct entry into the EHR, which can make preanalytical errors more difficult to identify.

Analytical processes. Quality assurance tasks related to the analytical process include training of staff, confirming staff competency, equipment maintenance, recording of patient results, inventory control, QC testing of instruments and reagents, proficiency testing, and documentation of processes to meet regulatory requirements.

One significant challenge, and a key to making POCT work, is training and ensuring staff competency. A standard operating procedure must be available for each assay, not only for staff to read as part of their training and ongoing competency but also as a reference for consultation on a regular basis. Even if test devices are operating perfectly, accurate test results will not be produced if staff are not educated about appropriate specimen collection and operation of test devices. Considering that training is one of the most important functions of a POCT coordinator, teaching skill is a prime factor to consider when hiring a POCT coordinator. It may be helpful to have self-instruction videos or Web-based instruction to supplement the hands-on instructor-led training. Some vendors of POCT products have recognized the critical role of training and assist with initial training of staff.

Most POCT devices require limited maintenance such as cleaning and battery replacement, but if this is neglected, devices may fail. Portable devices may be dropped or exposed to vibration, water, extremes of heat or cold, or other environmental challenges that may lead to equipment failure. In part, this is a training issue, but even with appropriate maintenance and use, periodic device failures are likely. The greater potential for equipment damage in an uncontrolled environment emphasizes the need for control processes to detect malfunctions of devices. Usually, failure of POCT devices is handled by replacement of the failed unit rather than attempts at recalibration or repair because the lower cost of an individual unit often does not justify a service agreement for repairs. This is handled by having one or more devices available as backups or by having a contingency plan for how service will be delivered. Lack of experience of the testing staff with troubleshooting equipment or reagent problems requires on-call support by POCT coordinators or other experts. The central laboratory may assist with troubleshooting, particularly with interferences or with systematic changes of analyzers or reagents that may be identified by comparison of test results from POCT and the central laboratory.

Control processes of POCT ideally should assess equipment, specimens, reagents, and testing personnel. Some POCT equipment executes automatic built-in internal

本书版权归John Wiley & Sons Inc.所有

checks of electronic components, batteries, photometers, and other components with each use of the device. Mechanisms may exist for detecting specimen problems, such as inadequate specimen volume, clots, or bubbles. Many devices that are interpreted by direct visual inspection, such as tests for fecal occult blood, pregnancy, and other rapid antigen and antibody tests, have internal procedural controls that indicate whether the individual device is operational and whether there is inadequate specimen or an interference with the test. These control processes are highly desirable for POCT and should be sought when selecting tests or equipment because they check the test or instrument, specimen, the testing personnel, and, in some cases, the reagents with each use.

The primary quality assurance focus of testing personnel and regulations usually is on external QC testing and proficiency testing. These external controls serve as additional checks for equipment, reagent failure, and testing personnel performance. However, standard QC processes are designed primarily to detect systematic shifts in performance over time, and these are less of a problem with POCT, where reagents and equipment often are stable for months. A standard from the Clinical and Laboratory Standards Institute (CLSI) on single-use devices has suggested that the frequency of QC testing should be 1/10 of the shelf life of reagents rather than the more customary testing per shift or per day (45). Standard QC processes are not well designed to detect sporadic failures of single-use devices and do not detect specimen problems. Some areas in which QC testing may make a positive contribution in the POCT environment are to evaluate and provide ongoing competency assessment of testing staff, to provide ongoing training of staff who infrequently perform a test, and to ensure the equipment is producing accurate results compared to a given standard. To achieve these benefits, it is important for external QC testing to be rotated among all staff, which is also a CLIA regulatory requirement in the United States for nonwaived testing (5).

As of 2016, an alternative approach acceptable to CLIA for determining external QC frequency was the option of implementing an Individualized Quality Control Plan (IQCP) (46). An IQCP can be highly beneficial to a POCT program with nonwaived testing in that the intention of an IQCP is to allow for reduced external QC frequency less often than the CLIA requirement, commonly two concentrations per day each day patient specimens are tested, if the manufacturer's QC requirement for the device is less than the CLIA minimum (47). Elements of an IQCP include the initial risk assessment, devising the quality control plan, and determining details of the quality assessment for ongoing evaluation that the plan is functioning correctly. The IQCP must be reviewed and approved by the CLIA laboratory director before implementation and yearly thereafter. One controversial issue that may arise due to an IQCP is whether using electronic simulators provided with some devices is an acceptable alternative to external QC materials (48). Advantages of using electronic controls are substantial reduction in the costs for test supplies and control materials, as the same electronic control can be used multiple times. Often, control testing represents as much as one-quarter to one-half of the total volume of testing at a low-volume testing site. Therefore, use of electronic simulators could reduce supply costs by as much as 50%. This reduction in costs may be critical to the economic viability of some testing activities in which unit costs of supplies are high. The major argument against the use of electronic simulators is that although they check performance of the electronic components of an analyzer, they do not check the performance of the reagents or testing personnel. If electronic simulators are used, there should be a mechanism to periodically check the appropriate function of the reagents, such as when new lots or shipments of reagents or cartridges are received. Also, because testing a simulator does not simulate the steps of testing a patient sample, an electronic simulator should not be used for staff training or competency evaluation.

Postanalytical processes. Areas to ensure quality of postanalytical processes for POCT include accurate result documentation, record keeping, proper communication and documentation of critical result communication, interpretation of results, review of test utilization and supply budgets, and accurate billing for testing activities.

Extensive record keeping is essential for meeting the regulatory and quality assurance requirements for POCT (44, 49). Historically, information was recorded manually and it was a struggle to achieve complete records of necessary data. Now that POCT has grown substantially, middleware is frequently used to collect and store information about control testing, patient results, and which testing personnel are authorized to perform and have performed testing. POCT software can be implemented to manage analyzer settings remotely, such as instrument software updates, setting QC acceptable values, and setting instrument lockout functions that require QC testing at defined intervals before patient testing can be performed. The implementation of these POCT software systems requires additional expense to pay for the interface between the software and LIS and/or EHR, as well as coordination with the IT department to install and verify proper functionality of the software prior to use for patient results. Downtime protocols must also be defined for when these systems go offline for planned or unplanned maintenance and downtime.

The specimen type or fundamental measuring principles of POCT devices often differ from those used in the central laboratory, which may be confusing to clinicians

本书版权归John Wiley & Sons Inc.所有

who are trying to interpret test results. Thus, it is important to perform comparisons of POCT and central laboratory results to understand how to manage their differences and support clinician education for interpretation. Efforts have been made to reach agreement on common reference methods to prepare standards, such as for total carbon dioxide measurement, to reduce the problem with comparison of POCT and laboratory results (50). However, the volume displacement and viscosity effects of red blood cells can still affect the reliability of results for whole blood specimens with extremely high or low hematocrits (51). Fundamental problems of comparability of methods may be experienced for POCT hematocrit measurements by conductivity versus laboratory measurements (52), and for POCT whole blood coagulation tests versus laboratory measurements on plasma specimens (53). Alternative capillary blood glucose testing sites, such as the palm, thigh, or forearm, may be less painful and acceptable alternatives if approved by the POCT device manufacturer. However, awareness of limitations—for example, decreased testing success rate—and contraindications to using these sites is important to using POCT of alternative sites effectively (54). The contraindication to alternative site testing is essentially when blood glucose is rapidly changing, such as during episodes of hypo- or hyperglycemia, of which the first hour after a meal or after exercise are examples, due to delays in blood glucose distribution among the capillary network (54, 55). Differences in testing technology can lead to differences in the interferences with POCT devices (56), so informing clinicians of any limitations and variation compared to central laboratory methods can improve result interpretation.

Practical approaches to manage nonequivalence between POCT and laboratory methods include (i) performing careful comparison studies with the central laboratory assays to guide device selection and to provide data about expected differences for clinicians, (ii) educating clinicians about differences, and (iii) reporting values of nonequivalent methods separately in laboratory reports and the EHR with appropriate reference intervals. However, it may be desired by clinicians to have POCT and laboratory values side by side in the EHR to provide ongoing comparison.

The decision to bill for POCT and the selection of billing methods are complex issues that will depend on the type of POCT offered and the entity offering the testing. Some organizations have decided not to bill for POCT, others have rolled these costs into a global service cost, and others have billed for individual tests. To perform billing, it is necessary to have effective information systems that can document ordering of the test, performance of the test, and patient diagnoses suitable for reimbursement. If there is some duplication of POCT and central laboratory testing, this could be identified as double billing unless determined to be a medically necessary confirmation of a POCT result. It may be necessary to review the frequency of testing on bills to prevent exceeding allowable limits and to review the Logical Observation Identifiers Names and Codes (LOINC) and billing codes for accuracy. Creating the necessary documentation and reconciling bills with rules for reimbursement are formidable challenges.

Evaluating key performance indicators in POCT. The purpose of KPIs is to monitor the quality of processes in a program. To employ KPIs effectively, monitoring needs to be planned, as well as have a realistic scope and number of objectives, a defined method and duration, and interpretation with limits for implementing an action plan (57). Example KPIs for POCT programs include percentage of test results reported in the EHR, which can address the global POCT process; percentage of results with error codes or issues with patient identifiers, which evaluates the preanalytical and analytical phases; and percentage of tests performed by the testing personnel with highest activity, which evaluates staff training, competency, and willingness to perform testing (57). Through monitoring these indicators, issues such as the need for further testing personnel training, inadequate handling of QC or patient samples, and recurrent instrument issues can be identified (57). For critical values, a POCT program might collect data on the frequency of critical value confirmation by repeat testing and proper documentation, as applicable to the policy. A study of 50 institutions found that critical glucose meter results were confirmed a median of 56% of the time and had documented communication to the healthcare provider a median of 86% of the time (58). The authors' recommendations from these data were to provide adequate training and visual aids, and to audit the process to ensure compliance in addition to developing guidelines for POCT standardization for handling critical values.

An alternative or additional means of assessment can be through applying Six Sigma concepts. Six Sigma uses data statistical analysis to identify causes of defects or variation during manufacturing so they can be corrected to improve product quality. A goal of Six Sigma is to achieve stable and predictable processes so they become "world class" with error rates less than or equal to 3.4 errors per million products produced, which corresponds to a Six Sigma score of 6 or higher. An example of applying Six Sigma concepts to POCT was published by Vincent et al. They performed Six Sigma analysis of a variety of quality indicators for glucose concentration measured using 158 glucose meters (59). The Six Sigma values for different preanalytical, analytical, and postanalytical processes for the glucose meters ranged from extremely low, at Six Sigma value of 0.5 for noncompliance with the hospital policy for

本书版权归John Wiley & Sons Inc.所有

repeating critically low or high results, to a good Six Sigma value of 4.7 for limited failures in the external quality control program. With this information, a focus can be placed on improvement efforts for processes with the lowest Six Sigma score but at highest risk for impacting patient safety.

Technological Management of POCT

POCT Innovation

Historically, POCT was limited by the small menu of tests available and by the relatively poor analytical quality of tests compared to central lab instruments. However, advances in technology and successful miniaturization of devices have made it technically feasible to perform virtually any test as POCT (49). Ongoing advances in the microfabrication of devices and in nanotechnology have provided technological change and further reduction in the size of POCT devices. Miniaturization of testing devices alone is not sufficient to make a test suitable for POCT. It is also important to reduce analysis times, to simplify the operation of test devices, and to minimize requirements for specimen preparation. To be suitable for POCT, a test usually must accept an unprocessed sample such as whole blood and the analysis times must be less than about 15 minutes. If these conditions are not met, it is difficult to perform the procedure as POCT, or the advantage in turnaround time of POCT versus central laboratory testing is not sufficient to provide a strong advantage for POCT.

The high rate of change and innovation in POCT devices presents a management challenge to stay abreast of information about these products. When advertisements and salespeople tout the latest and greatest new POCT devices and tests, how can an organization evaluate these claims? There are continuous upgrades for existing POCT devices, so a vendor of devices currently in use in an organization is likely to propose or require an upgrade when a change in the product is made and the old product is discontinued. It can be challenging for laboratory staff to be knowledgeable about the characteristics of a wide range of new POCT devices, many of which are not used in central laboratory settings. Technologies and performance characteristics may differ from central laboratory analyzers, and extensive track records of clinical use and published evaluations may be lacking. For the most current information about individual products, it may be necessary to consult with both vendors and other users.

At the same time as there has been rapid evolution of the analytical capabilities of POCT devices, there have been major changes in quality assurance processes, internal data systems, and the ability to transmit data to central information systems. The CLSI POCT1-A2 Connectivity Standards, published in 2006, set out common guidelines allowing for the standardization of POCT device connectivity to the LIS, EHR, and hospital information system. They also developed standardization guidelines for manufacturers of POCT devices. This prompted the development of data management systems which can connect to devices from multiple manufacturers (60). How devices link to information systems has become an increasingly important consideration in the evaluation and selection of devices. Connectivity to the EHR should be one of the first considerations in selecting a POCT device; it not only reduces result turnaround time, but it also reduces postanalytical transcription errors. The functionality of POCT middleware to LIS connectivity should be evaluated next. Bidirectional connectivity allows for the global management of a POCT program, including but not limited to device performance, quality assurance management, and testing personnel certification and competency, all of which are essential for the successful implementation and operation of a POCT program (61).

Pandemics, Mass Casualties, and Humanitarian Emergencies Driving POCT Innovation

Responding to pandemics, mass casualties, and humanitarian emergencies presents unique challenges across all aspects of patient care, including laboratory testing. During these events, POCT can be extremely beneficial, as it provides rapid results when quick decision making is essential to patient outcome (62–64). The same considerations in building a POCT program need to be evaluated in preparing POCT as part of emergency preparedness. What tests, and subsequently what analyzers, are needed? Do the tests have adequate analytical sensitivity and specificity? Who is going to collect and test the samples? How are results communicated to clinicians? The discussion around these questions should include a multidepartmental committee for facility mass casualty planning, or national and international groups for humanitarian emergencies preparedness, to ensure all needs are evaluated and met (62, 64). While hospital systems are becoming more accustomed to POCT, it has been reported, after both the Ebola and COVID-19 pandemics, that public health programs and public health schools in the U.S. need to improve incorporation of POCT skills and preparedness into their curricula to ensure an adequate response to these crises (65, 66). POCT innovation can be driven by the demand to use POCT for these kinds of emergencies.

At the onset of the COVID-19 pandemic, large-scale and widespread testing was needed to identify positive cases, often overwhelming the staff and supply capacities of central laboratories. This led to the rapid development and growth of POCT used to diagnose COVID-19. Specimens for POCT often required less specialized collection and processing techniques, helping alleviate bottlenecks and

本书版权归John Wiley & Sons Inc.所有

provide faster results (63). Molecular-based testing is recommended for detecting active infections, compared to the less sensitive antigen testing (67). Due to the technical requirements of the test methodology, antigen testing initially was easier to translate to the POCT environment; however, many successful molecular-based POCT products have been developed as well. As of mid-2022, in the United States, over 40 tests utilizing either the gold standard reverse transcription PCR or isothermal amplification have received Food and Drug Administration Emergency Use Authorization for use at the point of care. These tests still fall under the oversight of CLIA regulations for waived and moderately complex testing and are intended for use in healthcare settings (63, 68). Lessons learned during the COVID-19 pandemic should be applied in responding to future strains or new outbreaks. Underserved communities and people of color were disproportionately impacted by COVID-19 where access to testing and care was limited (69, 70). If properly utilized, POCT could alleviate this burden in the future by reaching these communities that need it the most.

New Monitoring Technologies

Since the late 1990s, there has been rapid growth and development in wearable personal devices that perform both physiological monitoring and biological measurements (71). Given the global prevalence, there have been large investments into developing new blood glucose monitoring for improved user experience and disease management for people living with diabetes (72).

Careful blood glucose monitoring is key to proper diabetes management. This is commonly performed by using a lancet to prick the patient's finger and sampling capillary blood inserted into a blood glucose monitor (BGM). Continuous glucose monitors (CGM) have been developed in an attempt to move away from invasive sampling. However, most CGMs commercially available today are still minimally invasive as they involve inserting a small needle or probe within the patient's skin to measure glucose in the interstitial fluid. They also cannot completely replace fingersticks for blood glucose determination due to the clinical differences between blood and interstitial glucose levels (73–75). Yet, CGMs still have advantages over traditional blood glucose monitoring—CGMs can transmit results to the wearer's smartphone to provide real-time data regarding their glucose management, as well as connect to insulin pumps that automatically adjust the dosage based on the results. Use of CGMs for insulin-dependent diabetes has been shown to improve blood sugar levels and reduce the risk of hypoglycemia (74, 76). There is a wide range of methodologies being developed for fully noninvasive CGMs, ranging from reverse iontophoresis to multisensor technology, but these also come with varying degrees of accuracy and reliability (75, 77).

Monitoring technologies pose new challenges in the interpretation of test results. First, accuracy and performance characteristics of these devices historically differed substantially from those delivered by usual laboratory tests (75). Today, to meet FDA approval, BGMs, including CGMs, must measure within 15% of the laboratory value at least 95% of the time and within 20% of the laboratory value at least 99% of the time (78). Clinician and patient perception of device accuracy shortcomings could be a hindrance to realizing the full clinical potential of these devices (79). Second, as discussed, some CGMs measure concentrations in tissue or interstitial fluids rather than in plasma or blood. Consequently, there are physiological differences in the specimens sampled (73, 79). Third, the question is raised of whether, and how, these results should be incorporated into a patient's EHR. For accurate incorporation of results into the EHR, it is important for an organization using monitoring devices to perform comparison studies versus traditional laboratory methods. In addition, CGMs provide more results due to the frequent measurements compared to intermittent testing using a blood glucose meter. Proper clinician and patient education on these nuances of monitoring technologies is essential for proper clinical utility (79).

With wearable personal devices becoming more accessible, the question arises of how to define the physiologic measurements they obtain. Federal regulations in the United States define laboratory tests as procedures in which specimens are removed from the body for analysis (80). Therefore, glucose measurement performed on a device attached to a patient, such as CGMs, is not a laboratory test, but should it be? Regardless of whether these devices are officially classified as laboratory tests or not, processes and management structures developed for POCT may be effective mechanisms for supporting monitoring devices, even if these are not covered by the same regulations as traditional POCT.

SUMMARY

POCT presents some of the greatest and most complex organizational, operational, and technological challenges for laboratory professionals. POCT often crosses traditional organizational boundaries, encompasses testing activities performed at numerous different sites, and requires training and coordination of many staff who often have limited experience in performing laboratory tests. One of the most debatable issues is whether POCT costs more or leads to lower costs relative to central laboratory testing. There is evidence that POCT can reduce total organizational costs in certain circumstances. POCT is also one of the most dynamic and rapidly changing fields of diagnostic testing, driven by rapid technological change as well as evolving clinical demands. Through collaboration

本书版权归John Wiley & Sons Inc.所有

and effort, solutions can be found to the complex issues of POCT that are universally applicable to varying organizational structures, laboratory operations, and clinical demands for testing. With some organizational and operational hurdles to face, a POCT program that involves laboratory professionals will be well positioned to maintain focus on and achieve the goals of using POCT to improve quality, efficiency, and access to patient care and to increase clinician, healthcare staff, and patient satisfaction.

KEY POINTS

- POCT has some similar and unique management considerations compared to other types of laboratory testing.
- Providing an accurate cost analysis of POCT is challenging due to the use of different cost analysis methods and the inability to objectively measure some facets of POCT, such as staff productivity or clinician and patient satisfaction.
- Benefits of POCT include lower organizational costs in selected circumstances and improved access to healthcare for underserved populations.
- POCT scope is continually and rapidly changing due to advances in test methods and information technology.

GLOSSARY

Clinical and Laboratory Standards Institute (CLSI) A global, not-for-profit organization that is recognized by laboratories, accreditors, and government agencies for developing worldwide laboratory standards (clsi.org/).

College of American Pathologists (CAP) An organization of pathologists serving patients, pathologists, and the public worldwide by fostering excellence in pathology and laboratory medicine through providing external proficiency testing and accreditation services (cap.org/about-the-cap).

COLA Inc. (formerly Commission on Office Laboratory Accreditation) An organization that provides clinical laboratory education, consultation, and accreditation services primarily for physician office laboratories (cola.org/).

Full-time equivalent (FTE) A labor component equivalent to the time worked by one full-time employee on a standard schedule.

Macrocost analysis Analysis of costs by breaking down overall budgetary costs.

Microcost analysis Analysis of costs by adding up costs for performing an individual test.

Monitoring devices Devices that are attached directly to a patient and that provide periodic or continuous measurements.

Provider-performed microscopy Microscopic examinations such as potassium hydroxide preps and wet preps performed by primary care physicians outside the laboratory setting.

Six Sigma A strategy that uses data statistical analysis to identify causes of defects or variation during manufacturing so they can be corrected to improve product quality. Manufacturing encompasses any process that produces a product or service that can be evaluated.

The Joint Commission An organization that accredits healthcare facilities and components of their services such as laboratory testing (jointcommission.org/).

Waived testing Laboratory testing with the lowest level of complexity that can be performed under a certificate of waiver.

ACKNOWLEDGMENTS

The authors gratefully acknowledge the contributions of Glen L. Hortin and Christopher D. Doern to this chapter in previous editions.

REFERENCES

1. **College of American Pathologists**. 2017. *Point-of-Care-Testing Checklist*. College of American Pathologists, Northfield, IL.

2. **Swain R, Kharad S**. 2022. Point of care testing market. Global Market Insights Inc. https://www.gminsights.com/industry-analysis/point-of-care-testing-market. Accessed 16 July 2022.

3. **Jones BA, Howanitz PJ**. 1996. Bedside glucose monitoring quality control practices. A College of American Pathologists Q-Probes study of program quality control documentation, program characteristics, and accuracy performance in 544 institutions. *Arch Pathol Lab Med* **120**:339–345.

4. **Steindel SJ, Granade S, Lee J, Avery G, Clarke LM, Jenny RW, LaBeau KM**. 2002. Practice patterns of testing waived under the Clinical Laboratory Improvement Amendments. *Arch Pathol Lab Med* **126**:1471–1479.

5. **Code of Federal Regulations**. 2011. Clinical Laboratory Improvement Amendments (Title 42 USC 263a). https://www.govinfo.gov/content/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap6A-subchapII-partF-subpart2-sec263a.pdf. Accessed 17 July 2022.

6. **Centers for Medicare and Medicaid Services**. 2011. Certificate and regulatory multiple site exceptions under CLIA. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/CMS1254599. Accessed 14 August 2022.

7. **Jones BA, Bachner P, Howanitz PJ**. 1993. Bedside glucose monitoring. A College of American Pathologists Q-Probes study of the program characteristics and performance in 605 institutions. *Arch Pathol Lab Med* **117**:1080–1087.

8. **Hortin GI**. 1998. *Handbook of Bedside Glucose Testing*. AACC Press, Washington, DC.

9. **George S, Braithwaite RA**. 2002. Use of on-site testing for drugs of abuse. *Clin Chem* **48**:1639–1646.

10. **U.S. Department of Labor, Occupational Safety and Health Administration**. 2023. COVID-19 – Control and Prevention: Laboratory Workers and Employers. https://www.osha.gov/coronavirus/control-prevention/laboratory. Accessed 24 August 2022.

本书版权归John Wiley & Sons Inc.所有

11. **Lee-Lewandrowski E, Laposata M, Eschenbach K, Camooso C, Nathan DM, Godine JE, Hurxthal K, Goff J, Lewandrowski K**. 1994. Utilization and cost analysis of bedside capillary glucose testing in a large teaching hospital: implications for managing point of care testing. *Am J Med* **97**:222–230.

12. **Winkelman JW, Wybenga DR, Tanasijevic MJ**. 1994. The fiscal consequences of central vs distributed testing of glucose. *Clin Chem* **40**:1628–1630.

13. **Asimos AW, Gibbs MA, Marx JA, Jacobs DG, Erwin RJ, Norton HJ, Thomason M**. 2000. Value of point-of-care blood testing in emergent trauma management. *J Trauma* **48**:1101–1108.

14. **Boone JD, Hay JW, Aguanno J, Getzen T, Hortin G**. 2002. Are the correct economic factors influencing point-of-care testing? *Point Care J Patient Test Technol* **1**:212–221.

15. **Gruszecki AC, Hortin G, Lam J, Kahler D, Smith D, Vines J, Lancaster L, Daly TM, Robinson CA, Hardy RW**. 2003. Utilization, reliability, and clinical impact of point-of-care testing during critical care transport: six years of experience. *Clin Chem* **49**:1017–1019.

16. **Despotis GJ, Grishaber JE, Goodnough LT**. 1994. The effect of an intraoperative treatment algorithm on physicians' transfusion practice in cardiac surgery. *Transfusion* **34**:290–296.

17. **Johnson LR, Doherty G, Lairmore T, Moley JF, Brunt LM, Koenig J, Scott MG**. 2001. Evaluation of the performance and clinical impact of a rapid intraoperative parathyroid hormone assay in conjunction with preoperative imaging and concise parathyroidectomy. *Clin Chem* **47**:919–925.

18. **Wians FH Jr, Balko JA, Hsu RM, Byrd W, Snyder WH III**. 2000. Intraoperative vs central laboratory PTH testing during parathyroidectomy surgery. *Lab Med* **31**:616–621.

19. **Nichols JH**. 2006. *Evidence-Based Practice for Point-of-Care Testing NACB Guideline*. American Association for Clinical Chemistry, Inc, Washington, DC.

20. **Price CP, St John A, Kricka LJ (ed).** 2010. *Point-of-Care Testing: Needs, Opportunity, and Innovation*, 3rd ed. AACC Press, Washington, DC.

21. **Lingervelder D, Koffijberg H, Kusters R, IJzerman MJ**. 2021. Health economic evidence of point-of-care testing: a systematic review. *Pharmacoeconom Open* **5**:157–173.

22. **Kilgore ML, Steindel SJ, Smith JA**. 1999. Continuous quality improvement for point-of-care testing using background monitoring of duplicate specimens. *Arch Pathol Lab Med* **123**:824–828.

23. **Weber CF, Görlinger K, Meininger D, Herrmann E, Bingold T, Moritz A, Cohn LH, Zacharowski K**. 2012. Point-of-care testing: a prospective, randomized clinical trial of efficacy in coagulopathic cardiac surgery patients. *Anesthesiology* **117**:531–547.

24. **Schaden E, Kimberger O, Kraincuk P, Baron DM, Metnitz PG, Kozek-Langenecker S**. 2012. Perioperative treatment algorithm for bleeding burn patients reduces allogeneic blood product requirements. *Br J Anaesth* **109**:376–381.

25. **O'Connell S, Conlan C, Reidy M, Stack C, Mulgrew A, Baruah J**. 2020. The impact of point-of-care testing for influenza A and B on patient flow and management in a medical assessment unit of a general hospital. *BMC Res Notes* **13**:143.

26. **Alter DN**. 2021. Point-of-care testing for the emergency department patient: quantity and quality of the available evidence. *Arch Pathol Lab Med* **145**:308–319.

27. **Loten C, Attia J, Hullick C, Marley J, McElduff P**. 2010. Point of care troponin decreases time in the emergency department for patients with possible acute coronary syndrome: a randomised controlled trial. *Emerg Med J* **27**:194–198.

28. **Fitzgerald P, Goodacre SW, Cross E, Dixon S**. 2011. Cost-effectiveness of point-of-care biomarker assessment for suspected myocardial infarction: the randomized assessment of treatment using panel assay of cardiac markers (RATPAC) trial. *Acad Emerg Med* **18**:488–495.

29. **Wilson DP, Fairley CK, Sankar D, Williams H, Keen P, Read TRH, Chen MY**. 2011. Replacement of conventional HIV testing with rapid testing: mathematical modelling to predict the impact on further HIV transmission between men. *Sex Transm Infect* **87**:588–593.

30. **Rosen S, Fox MP**. 2011. Retention in HIV care between testing and treatment in sub-Saharan Africa: a systematic review. *PLoS Med* **8**:e1001056.

31. **HealthEuropa.** 2022. Enhancing access to healthcare with point-of-care diagnostics technology. https://www.healtheuropa.com/enhancing-access-to-healthcare-with-point-of-care-diagnostics-technology/113501/. Accessed 28 August 2023.

32. **Florkowski C, Don-Wauchope A, Gimenez N, Rodriguez-Capote K, Wils J, Zemlin A**. 2017. Point-of-care testing (POCT) and evidence-based laboratory medicine (EBLM): does it leverage any advantage in clinical decision making? *Crit Rev Clin Lab Sci* **54**:471–494.

33. **Kabra S, Kanungo R**. 2012. Monitoring quality of HIV testing at point of care facilities in India. *Indian J Med Microbiol* **30**:129–130.

34. **Shott JP, Galiwango RM, Reynolds SJ**. 2012. A quality management approach to implementing point-of-care technologies for HIV diagnosis and monitoring in sub-Saharan Africa. *J Trop Med* **2012**:651927.

35. **Rasti R, Nanjebe D, Karlström J, Muchunguzi C, Mwanga-Amumpaire J, Gantelius J, Mårtensson A, Rivas L, Galban F, Reuterswärd P, Andersson Svahn H, Alvesson HM, Boum Y II, Alfvén T**. 2017. Health care workers' perceptions of point-of-care testing in a low-income country: a qualitative study in Southwestern Uganda. *PLoS One* **12**:e0182005.

36. **Keizur EM, Goldbeck C, Vavala G, Romero-Espinoza A, Ocasio M, Fournier J, Lee S-J, Abdalian S-E, Rotheram MJ, Klausner JD, Adolescent Trials Network (ATN) CARES Team**. 2020. Safety and effectiveness of same-day Chlamydia trachomatis and Neisseria gonorrhoeae screening and treatment among gay, bisexual, transgender, and homeless youth in Los Angeles, California, and New Orleans, Louisiana. *Sex Transm Dis* **47**:19–23.

37. **Chambliss AB, Johnson G, Robinson J, Banerjee J, Feldman BJ**. 2021. Point-of-care testing to support a street medicine program in caring for the homeless. *J Appl Lab Med* **6**:330–332.

38. **Valencia J, Lazarus JV, Ceballos FC, Troya J, Cuevas G, Resino S, Torres-Macho J, Ryan P**. 2022. Differences in the hepatitis C virus cascade of care and time to initiation of therapy among vulnerable subpopulations using a mobile unit as point-of-care. *Liver Int* **42**:309–319.

39. **Salem JK, Jones RR, Sweet DB, Hasan S, Torregosa-Arcay H, Clough L**. 2011. Improving care in a resident practice for patients with diabetes. *J Grad Med Educ* **3**:196–202.

本书版权归John Wiley & Sons Inc.所有

40. Faal M, Naidoo N, Glencross DK, Venter WDF, Osih R. 2011. Providing immediate CD4 count results at HIV testing improves ART initiation. *J Acquir Immune Defic Syndr* **58**:e54–e59.

41. Jani IV, Sitoe NE, Alfai ER, Chongo PL, Quevedo JI, Rocha BM, Lehe JD, Peter TF. 2011. Effect of point-of-care CD4 cell count tests on retention of patients and rates of antiretroviral therapy initiation in primary health clinics: an observational cohort study. *Lancet* **378**:1572–1579.

42. Rossi AF, Khan D. 2004. Point of care testing: improving pediatric outcomes. *Clin Biochem* **37**:456–461.

43. Pecoraro V, Germagnoli L, Banfi G. 2014. Point-of-care testing: where is the evidence? A systematic survey. *Clin Chem Lab Med* **52**:313–324.

44. Kost GJ. 2001. Preventing medical errors in point-of-care testing: security, validation, safeguards, and connectivity. *Arch Pathol Lab Med* **125**:1307–1315.

45. Whitley RJ, Santrach PJ, Phillips DL. 2001. Establishing a quality management system for unit-use testing based on NCCLS proposed guideline (EP18-P). *Clin Chim Acta* **307**:145–149.

46. Centers for Medicare and Medicaid Services. 2021. Individualized Quality Control Plan (IQCP). https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP. Accessed 14 August 2022.

47. Quintenz A. 2015. IQCP: a new option for Quality Control. Medical Laboratory Observer. https://www.mlo-online.com/continuing-education/article/13008410/iqcp-a-new-option-for-quality-control. Accessed 14 August 2022.

48. Ehrmeyer SS, Laessig RH. 2001. Electronic "Quality Control" (EQC): is it just for unit use devices? *Clin Chim Acta* **307**:95–99.

49. Nichols JH. 2003. Quality in point-of-care testing. *Expert Rev Mol Diagn* **3**:563–572.

50. International Federation of Clinical Chemistry and Laboratory Medicine. IFCC Scientific Division, Working Group on Selective Electrodes. 2001. IFCC reference measurement procedure for substance concentration determination of total carbon dioxide in blood, plasma or serum. *Clin Chem Lab Med* **39**: 283–288.

51. Chmielewski SA. 1995. Advances and strategies for glucose monitoring. *Am J Clin Pathol* **104**(Suppl 1):S59–S71.

52. Stott RA, Hortin GL, Wilhite TR, Miller SB, Smith CH, Landt M. 1995. Analytical artifacts in hematocrit measurements by whole-blood chemistry analyzers. *Clin Chem* **41**:306–311.

53. Vazquez SR, Fleming RP, Johnson SA. 2017. Comparison of two point-of-care international normalized ratio devices and laboratory method. *Blood Coagul Fibrinolysis* **28**:534–539.

54. Bina DM, Anderson RL, Johnson ML, Bergenstal RM, Kendall DM. 2003. Clinical impact of prandial state, exercise, and site preparation on the equivalence of alternative-site blood glucose testing. *Diabetes Care* **26**:981–985.

55. Jungheim K, Koschinsky T. 2002. Glucose monitoring at the arm: risky delays of hypoglycemia and hyperglycemia detection. *Diabetes Care* **25**:956–960.

56. Kost GJ, Nguyen TH, Tang Z. 2000. Whole-blood glucose and lactate. Trilayer biosensors, drug interference, metabolism, and practice guidelines. *Arch Pathol Lab Med* **124**:1128–1134.

57. Oliver P, Fernandez-Calle P, Mora R, Diaz-Garzon J, Prieto D, Manzano M, Dominguez I, Buño A. 2020. Real-world use of key performance indicators for point-of-care testing network accredited by ISO 22870. *Pract Lab Med* **22**:e00188.

58. Schifman RB, Howanitz PJ, Souers RJ. 2016. Point-of-care glucose critical values: a Q-probes study involving 50 health care facilities and 2349 critical results. *Arch Pathol Lab Med* **140**:119–124.

59. Vincent A, Pocius D, Huang Y. 2021. Six Sigma performance of quality indicators in total testing process of point-of-care glucose measurement: a two-year review. *Pract Lab Med* **25**:e00215.

60. Erasmus R, Sahni S, El-Sharkawy R. 2021. Connectivity strategies in managing a POCT service. *EJIFCC* **32**:190–194.

61. Erasmus R, Sahni S, El-Sharkawy R. 2021. Connectivity strategies in managing a POCT service. *EJIFCC* **32**(2):190–194.

62. Neff Newitt V. 2019. Mass casualty plan puts point-of-care testing in the ED. CAP Today. https://www.captodayonline.com/mass-casualty-plan-puts-point-of-care-testing-in-the-ed/. Accessed 24 July 2022.

63. Valera E, Jankelow A, Lim J, Kindratenko V, Ganguli A, White K, Kumar J, Bashir R. 2021. COVID-19 point-of-care diagnostics: present and future. *ACS Nano* **15**:7899–7906.

64. Chadwick S, Townes DA, Perrone LA. 2021. Utility of point of care and rapid diagnostics in humanitarian emergencies. *J Appl Lab Med* **6**:236–246.

65. Kost GJ, Zadran A, Zadran L, Ventura I. 2019. Point-of-care testing curriculum and accreditation for public health-enabling preparedness, response, and higher standards of care at points of need. *Front Public Health* **6**:385.

66. Kost GJ. 2021. Public health education should include point-of-care testing: lessons learned from the Covid-19 pandemic. *EJIFCC* **32**:311–327.

67. Drain PK. 2022. Rapid diagnostic testing for SARS-CoV-2. *N Engl J Med* **386**:264–272.

68. U.S. Food and Drug Administration. 2023. In vitro diagnostics EUAs - molecular diagnostic tests for SARS-CoV-2. https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2. Accessed 2 August 2022.

69. Lieberman-Cribbin W, Alpert N, Flores R, Taioli E. 2021. Analyzing disparities in COVID-19 testing trends according to risk for COVID-19 severity across New York City. *BMC Public Health* **21**:1717.

70. Price-Haywood EG, Burton J, Fort D, Seoane L. 2020. Hospitalization and mortality among black patients and white patients with Covid-19. *N Engl J Med* **382**:2534–2543.

71. Winkelman JW, Tanasijevic MJ. 2002. Noninvasive testing in the clinical laboratory. *Clin Lab Med* **22**:547–558.

本书版权归John Wiley & Sons Inc.所有

72. World Health Organization. 2023. Diabetes. https://www.who.int/news-room/fact-sheets/detail/diabetes. Accessed 29 July 2022.

73. Cleveland Clinic. 2021. Continuous glucose monitoring. https://my.clevelandclinic.org/health/drugs/11444-glucose-continuous-glucose-monitoring. Accessed 3 August 2022.

74. O'Kane MJ. 2020. Patient self-testing in chronic disease management. *J Lab Med* **44**:81–87.

75. Dias D, **Paulo Silva Cunha J.** 2018. Wearable health devices: vital sign monitoring, systems and technologies. *Sensors (Basel)* **18**:2414.

76. Freckmann G. 2020. Basics and use of continuous glucose monitoring (CGM) in diabetes therapy. *J Lab Med* **44**:71–79.

77. Sobel SI, **Chomentowski PJ**, **Vyas N**, **Andre D**, **Toledo FGS**. 2014. Accuracy of a novel noninvasive multisensor technology to estimate glucose in diabetic subjects during dynamic conditions. *J Diabetes Sci Technol* **8**:54–63.

78. U.S. Food and Drug Administration. 2020. Guidance document. Self-monitoring blood glucose test systems for over-the-counter use, FDA-2013–D-1446. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/self-monitoring-blood-glucose-test-systems-over-counter-use. Accessed 2 July 2022.

79. Heinemann L. 2018. Continuous glucose monitoring (CGM) or blood glucose monitoring (BGM): interactions and implications. *J Diabetes Sci Technol* **12**:873–879.

80. Ehrmeyer SS, **Laessig RH**. 1995. Regulatory requirements (CLIA '88, JCAHO, CAP) for decentralized testing. *Am J Clin Pathol* **104**(Suppl 1):S40–S49.

本书版权归John Wiley & Sons Inc.所有

23

Introduction
Preanalytic Activities
Test Selection and Implementation • Appropriate Test Utilization • Specimen Acquisition, Transport, and Storage • Test Ordering
Postanalytic Activities
The Report • Storage and Retention • Assessment of Test Results on Patient Outcomes
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENTS
REFERENCES

Principles of Preanalytic and Postanalytic Test Management

Lynne S. Garcia and Andrea J. Linscott

OBJECTIVES

To familiarize readers with the principles of selection, assessment, and incorporation of diagnostic tests

To review principles of test evaluation and utilization and their effect on patient outcomes

To describe major elements of requisition and test menu formats

To review principles of formatting of reports of test results

To review the necessity for report interpretation and consultation comments

To review the needs for record storage

When you are called to a sick man, be sure you know what the matter is—if you do not know, nature can do a great deal better than you can guess.

NICHOLAS DE BELLEVILLE

THE PRIMARY FUNCTION OF A CLINICAL laboratory is to provide accurate, clinically relevant data for the diagnosis of medical conditions in patients. Once available, the data can be used to provide the individual patient a management plan to increase the probability of achieving a desirable outcome (1). The production of laboratory data is a culmination of sequential processes constituted of preanalytic, analytic, and postanalytic laboratory activities that begin with a clinician's request for specific studies on an individual patient (2). Such sequential processes are also known as "path of workflow" and have been described and defined by the Clinical and Laboratory Standards Institute (CLSI; previously called National Committee on Clinical Laboratory Standards or NCCLS) and Clinical Laboratory Improvements Amendment (CLIA) regulations (Table 23.1).

The quality of service provided by a laboratory can impact patient care outcomes either positively or negatively (1). To achieve optimal patient outcomes, it is imperative to evaluate the effect of preanalytic and postanalytic activities on the clinical relevance and medical impact of laboratory tests (3).

Processes and procedures implemented within the laboratory should be understood as to their impact on workflow. Their design should have the level of quality needed to minimize errors and resource waste while maximizing efficacy. Quality standard guidelines and regulatory accreditation

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch23.

本书版权归John Wiley & Sons Inc.所有

Table 23.1 Processes in the clinical laboratory: path of workflow[a,b]

Process type	Description or definition
Preanalytic	Steps taken before test is performed (pre-examination phase). Processes beginning with test request and its format, patient preparation, specimen collection, specimen transportation, specimen receipt in the laboratory and preparation for testing (specimen processing)
Analytic	Activities related to the performance of laboratory testing or examination of specimens (examination phase)
Postanalytic	Steps that occur after a laboratory test has been performed (postexamination phase). Processes include data review, report formatting, result interpretation and presentation, permission for release, result transmission, and sample storage.

[a] Path of workflow: sequential sum of all preanalytical, analytical, and postanalytical processes, beginning with test order and culminating with laboratory data output.
[b] Compiled from references 2 and 5.

Table 23.2 Partial list of guidelines and regulatory accreditation requirements[a]

Test method validation
Accuracy
Precision
Analytic sensitivity (lower level of detection)
Analytic specificity
Reportable range
Reference range
Verification of FDA-approved tests
Retention of validation/verification data
Proficiency testing
Personnel requirements
Competency of personnel
Reporting of critical results (critical list)
Computer system accuracy checks
Format of reporting corrected reports
Written procedure or protocol

[a] Developed with input from more than 500 pathologists and laboratory experts, the CAP 21 discipline-specific accreditation checklists provide a clear roadmap not only for achieving accreditation but also for running a high-quality laboratory (https://www.cap.org/laboratory-improvement/accreditation/accreditation-checklists, accessed 28 July 2023).

requirements have been published and need to be met (Table 23.2) (4–9).

It is not adequate to evaluate tests solely from the laboratory-centered perspectives of accuracy, rapid turnaround time, low cost, and high sensitivity/specificity. Rather, to achieve the highest quality in all processes, laboratory management must be dedicated to the continuous assessment of both pre- and posttesting of all laboratory studies.

The laboratory medical director should be responsible for the assessment of test results on patient outcomes and therapeutic protocols (10). After careful test selection and implementation, the laboratory should evaluate both test utilization and appropriateness of test ordering to achieve the most positive effect on patient outcomes and cost-effectiveness. After laboratory testing, various actions or interventions may occur that are not under laboratory control. To ensure quality care and follow-up for the patient, it is important for laboratory management to interact with teams of nonlaboratory specialists, including infectious disease clinicians, hospitalists, infection control epidemiologists, radiologists, pharmacists, clinical case managers, and the nursing staff. The reporting format of test results and the accompanying report comments and interpretation also play crucial roles in assisting clinicians to best serve their patients.

Preanalytic Activities

The preanalytic phase refers to all steps taken before actual testing is performed on a patient's specimen. It includes test selection, test ordering, patient/specimen preparation/identification, specimen collection and transportation, and specimen processing and preparation, as well as appropriate specimen storage prior to testing. Referral of specimens to reference laboratories for additional or otherwise esoteric testing is included in this phase. Processes must be maintained for the assessment of all preanalytic activities. Business management strategies such as application of Six Sigma practices and the College of American Pathologists (CAP) Q-Probes and Q-Tracks Programs (11) may further assist in the analysis of laboratory processes for appropriateness and efficacy (12).

Test Selection and Implementation

Test complexity. The Clinical Laboratory Improvement Amendments were passed by Congress in 1988 (CLIA '88) to establish quality standards for laboratory testing and to ensure the accuracy, reliability, and timeliness of patient test results. Initially, laboratory tests were categorized by CLIA '88 as either waived, moderate complexity, or high complexity. However, a "final rule" published in the *Federal Register* in 2003 recognized only two classifications of laboratory tests: waived and nonwaived (13). Thus, the original classifications of moderate complexity and high complexity were combined under the classification of "nonwaived testing." Waived tests are defined as simple laboratory examinations and procedures that are cleared for home use by the U.S. Food and Drug Administration (FDA), have simple methodologies, or pose no reasonable risk of harm to the patient if performed incorrectly (5). Nonwaived tests (both moderate and high complexity) have more difficult methodologies and, with one exception, more rigorous regulatory requirements. The exception is the differing levels of training required for personnel performing either moderate- or high-complexity testing. When determining whether to add a specific test to the

本书版权归John Wiley & Sons Inc.所有

menu, laboratories must decide into which of these categories the test fits and whether the laboratory meets the requirements to perform this level of testing. Further information regarding categorization of tests can be found at the FDA website at https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-categorizations. Laboratories performing nonwaived testing must be certified or licensed under CLIA regulations. They must operate with guidelines in place for proper patient test management and must set specifications for all areas that can impact specimen integrity and positive identification throughout preanalytic, analytic, and postanalytic processes. The laboratory must maintain an adequate number of qualified employees to perform these tests (5).

Types of tests. At the most basic level, laboratory tests are tools to gain information about a patient (14). Tests are commonly ordered for a variety of reasons, including diagnosis, screening for disease, and patient management (Table 23.3) (15). Tests are ordered for establishing a baseline, assessing prognosis, reassuring patients, and helping with treatment decisions. Appropriateness of ordering and effects of testing often go beyond diagnosis or immediate treatment decisions in this setting (14). Understanding testing needs from the clinician's point of view can help in developing strategies to optimize patient care while at the same time enhancing cost-effectiveness. Testing that may appear unnecessary to the laboratory may be based on physical findings known only to the clinician (16).

The diagnostic process in patient care is critical in that it leads to prognosis and treatment (15). A clinician may inappropriately order diagnostic tests because the tests appear to pose minimal risk while providing possible useful information. Ordering overuse may burden the laboratory unnecessarily, may cause the patient avoidable harm, and does not contribute to improved quality of medical care, shorter hospital stays, or reduced mortality (17). An unexpected result may lead to unnecessary additional testing or inappropriate care for a particular patient (15). Even for a healthy person, the more tests ordered, the greater the probability that some results will fall outside the "normal" range. Table 23.4 lists the properties of useful diagnostic tests (18, 19).

Clinically relevant screening tests (such as lipid panels for evaluation of risk for coronary artery disease, PSA for prostate cancer, and carriage of group B *Streptococcus* during the 36th–38th week of pregnancy as a risk factor for neonatal infection during delivery after premature rupture of membranes [20]) are those that may show previously undetected disease in asymptomatic people or identify risk factors for a disease (15, 19). Table 23.5 lists various parameters for the ideal setting for diagnostic screening tests. When these criteria are applied to measure the efficacy of screening tests, it becomes evident that only a few such tests are appropriate and only for a handful of diseases. People shown to have an increased risk of disease by a screening test are usually advised to consult a physician for follow-up when appropriate (21).

Input from clinicians and other healthcare providers is vital for the best possible selection of tests. Diagnostic and monitoring criteria can be established through collaboration with specialists in each area of clinical practice. From these criteria, essential tests for a particular clinical setting can be chosen. It is also crucial to work with managed-care leaders, case managers, contract providers, insurance payors, and government representatives, as certain types of testing may not be covered by insurance or other financial reimbursement. Needs assessment should also consider the testing environments, of which there are many more

Table 23.3 Applications of laboratory tests[a]

Basic screening
Establishing (initial) diagnosis
Differential diagnosis
Estimating prognosis
Evaluation of current medical case management and outcomes
Evaluating disease severity
Detecting disease recurrence
Monitoring course of illness and response to treatment
Selecting drugs and adjusting therapy
Group and panel testing (often with authorized "reflex" testing)
Regularly scheduled follow-up tests as part of ongoing care
Testing responding to specific events or certain signs and symptoms (such as sexual assault, drug screening, postmortem)

[a] Adapted from references 14 and 19.

Table 23.4 Properties of useful diagnostic tests[a]

Methodology is well described and easily reproducible.
Accuracy and precision have been ascertained.
Reference range is established.
Sensitivity and specificity established based on an appropriately wide spectrum of clinical presentations and patient types (including age where necessary).

[a] Adapted from references 14 and 19.

Table 23.5 Parameters for ideal settings for screening tests

Characteristics of population
Sufficiently high prevalence of disease
Likely to be compliant with subsequent tests and treatments
Characteristics of disease
Significant morbidity and mortality
Effective and acceptable treatment available
Presymptomatic period detectable
Improved outcome from early treatment
Characteristics of test
Good sensitivity and specificity
Low cost and risk
Confirmatory test available if necessary and practical

[a] Adapted from reference 19.

本书版权归John Wiley & Sons Inc.所有

options than in the past. Testing may be done "in the field," commonly known as point-of-care, or may be done in a clinician's office, clinic, hospital, or freestanding diagnostic facility (14). Collection of specimens or administration of some tests may require hospital admission, albeit normally as outpatient status.

There is increasing interest in patient-directed orders for testing, both by consumers and laboratories. Direct access testing (DAT) is initiated by an individual patient, without evaluation or order by a clinician (22). Results are returned directly to the patient ordering the test rather than to a clinician. Reimbursements for DAT come directly from the patient and not from third-party payors (e.g., Medicare, managed-care plans). DAT is becoming increasingly popular based on a more proactive health-conscious society. Avoiding the cost of the copay or the cost of the entire physician visit is another reason that DAT is becoming popular in the outpatient setting. Self-initiated testing is a natural progression to testing offered at health fairs and home test kits (23).

Laboratories must develop an awareness of some of the issues related to offering DAT (Table 23.6). Many states allow test ordering and result release only to appropriately licensed practitioners. State regulations must be reviewed to ascertain local regulatory constraints, if any, on releasing results to unauthorized people, including the patients themselves. Many of the tests performed at DAT centers are classified as waived. However, there are tests offered at these facilities that are categorized as nonwaived, requiring stringent regulatory compliance. Laboratories considering offering DAT may damage their relationships with their physician clients. Although it appears that corporations are welcoming this type of testing as a business opportunity, physicians may be more concerned about its ramifications and effects. Laboratories will have to find ways to bridge the gap between these differing opinions.

Table 23.6 Pros and cons of direct access testing (DAT)[a]

Pros	Cons
Allows patients to keep sensitive test results out of medical records or away from insurers if desired	Potential to have negative impact on health status for certain patients
Empowers consumers to take charge of their own health	Potential to leave patient's physician unaware of conditions or problems that need care or attention
Opportunity to reduce costs by eliminating the middleman	False positives or false negatives may have adverse impact on patient health
Gives educated patients opportunity to be involved in managing and monitoring their own health	Physicians may have less control over patient management
Makes it easier for patients with chronic conditions to be involved in monitoring; could reduce unnecessary physician visits	Potential to play into patient hypochondria
Testing not limited by geography of provider	Potential for charlatans to take advantage of uninformed consumers
	Testing costs may be higher because they are not negotiated by an insurance company
	Self-collected specimens may adversely affect test result
Other considerations:	
Testing laboratories need to establish clear lines of communication when providing results to patients.	
Individual state regulations may differ and need to be closely examined.	
DAT testing is often not covered by insurance providers; patients must be made aware.	
Concerns may be addressed through education, regulation, oversight, and enforcement.	

[a] See references 34 and 62.

Test nomenclature. A standardized vocabulary for a test name is becoming more important with the expansion of computerized clinical provider order entry. Consistent terminology avoids confusion regarding what test should be ordered and can provide a test menu catalog that will be the same in different healthcare organizations. It is important to recognize that terminology for requesting may be different from that for resulting. For example, the single request "Liver Function Tests" may generate six or more individual results depending on the laboratory. In addition, a single request may require more than one sample type; for example, creatinine clearance requires both serum and 24-hour urine samples. Furthermore, adoption of international recommendations for testing requires unambiguous terminology.

Two international standards for terminology are Logical Observation Identifiers Names and Codes (LOINC) (https://loinc.org/get-started/what-loinc-is/, accessed 10 October 2022) and SNOMED CT (Systematized Nomenclature of Medicine—Clinical Terms; https://www.techtarget.com/searchhealthit/definition/SNOMED-CT, accessed 10 October 2022). These standards are also used for results reporting.

Test sensitivity, specificity, and predictive values. The parameters of the sensitivity, specificity, and predictive value of a test describe the clinical value of a test. Test results must always be interpreted in a clinical setting, considering the patient's history and physical examination findings when applicable. Without clinical relevance interpretation, the results, even if they are technically accurate, may not have meaning for the patient or practitioner (14, 15, 24, 25). Sensitivity is the ability of a test to correctly identify patients with a disease. Specificity is the ability of a test to correctly identify people without the disease. A true positive indicates that the person has the disease and the test is positive. A true negative means the person does not have the disease and the test is negative. Expressed as a formula, percent sensitivity is the percentage of people

本书版权归John Wiley & Sons Inc.所有

with the disease/analyte who test positive using the test in question, divided by the total number of people tested with the disease, multiplied by 100. Minimizing false positives is important when the costs or risks of follow-up therapy are high and the disease itself is not life-threatening. False negatives are problematic if the disease is often asymptomatic, is serious, progresses rapidly, and can be treated more effectively at early stages, or easily spreads from one person to another.

Specificity shows the percentage of individuals who do not have the disease being tested and for whom negative test results are found (14, 24). Expressed as a formula, percent specificity is the percentage of people without disease who test negative with the test in question, divided by the total number of people without the disease, multiplied by 100.

While sensitivity and specificity do not change with various populations of unwell or healthy people, predictive values can vary considerably depending on the prevalence of disease in the population that is being tested. If patients in a high-prevalence population are tested, it is more likely that those who test positive truly have the disease than if they are within a population with low prevalence. The positive predictive value provides the probability that a positive result indicates the presence of disease. Conversely, the negative predictive value provides the probability that a negative result indicates the absence of disease.

Test reimbursement. To remain viable, laboratories need to be reimbursed appropriately for the testing they perform. In most instances, for a test to be reimbursable by Medicare and other third-party payors it must have been reviewed and approved by the FDA. The test must also have received recognition by the American Medical Association (AMA) by being assigned to the code book of current procedural terminology (CPT) by the AMA's CPT committee; it often takes a year or longer for an approved test to receive a designated CPT code for billing purposes. When a laboratory performs a test that is deemed experimental by the AMA or is not approved by the FDA, the Centers for Medicare and Medicaid Services (CMS), previously known as Health Care Financing Administration (HCFA), will not allow reimbursement for that test, and Medicare will not reimburse the laboratory for that test. Managed-care providers generally follow this pattern as well. Thus, laboratory managers must review the AMA's official CPT code book, which is published and updated yearly, to keep current with the available chargeable tests. Failure to do so may compromise the financial viability of the laboratory due to the performance of tests whose expense is not reimbursed. Beyond the initial evaluation, it is imperative to consistently monitor the reimbursement of frequently ordered tests. Laboratories need to reevaluate the reimbursement of individual tests and to use this during negotiation for managed-care contracts to be appropriately compensated and to continue offering the tests. Multiplex PCR reimbursements may be problematic for Medicare or other insurance payments for analytes deemed not necessary for the diagnosis and treatment of illness or in the absence of signs and symptoms of disease (26).

Available technology. Advancements in science and technology will continue to allow laboratories to increase and enhance test menus. Improvements in diagnostic capability and decreasing turnaround times (TATs) have led to "real-time" diagnostic results, in which early intervention can dramatically improve patient outcomes. Molecular-based technology and computerized automation will continue to improve diagnostic capability. Often, clinicians request diagnostic tests whose overall effect and efficacy on patient care have not been well evaluated and whose reimbursement by third-party payors is in doubt. It is imperative that the laboratory evaluate such innovations and categorize them as to clinical and diagnostic efficacy and financial feasibility. Fiscal as well as clinical responsibility is paramount when making decisions on implementing tests (Table 23.7).

Cost studies. Cost-benefit analysis is a very important step in the assessment for test implementation. Several methods are available to assist with the cost accounting process. The instrument cost accounting technique was published by Travers in 1989 and is presented elsewhere in detail (9). This method considers instrument-related costs,

Table 23.7 Factors affecting the decision to implement or discontinue a test

Category	Reasons to implement	Reasons to discontinue
CLIA	Have staff with adequate education and experience Have system to ensure accurate results	Staff fails to meet CLIA guidelines
Managed care/ Medicare reimbursement	Assay reimbursed by Medicare and managed care	Inability to obtain adequate reimbursement from managed care or Medicare
Testing technology	Ease of use with test kits More readily obtained Technology advanced	Testing becomes obsolete Manufacturers discontinue test kits/reagents
Cost-effective	High-volume ordering Increase in reimbursements from managed care	Test volumes too low

本书版权归John Wiley & Sons Inc.所有

direct materials costs, and labor costs. The process is sufficiently generic to apply to any department in the laboratory. As the cost for each test is determined, total costs for patterns of disease-related groupings can be calculated.

Procedural analysis can also be implemented using published CLSI (NCCLS) guidelines (27). These guidelines include methods for analysis that can justify the addition of new procedures, assist in determining the frequency of test runs, and supply information regarding the performance of laboratory personnel or instrumentation. The guidelines provide in-depth definitions of terms, numerous sample forms, examples of different scenarios, relevant variables, and frequently asked questions. The importance of first having a functional model of the laboratory in place is emphasized. The model should include component working instruments and laboratory cost centers, as well as availability of ancillary data from finance, payroll, and purchasing departments.

Screening is an important part of preventive medicine. Ideally, screening tests identify patients early enough to provide treatment and avoid or reduce symptoms and other consequences, improving health outcomes of the population at a reasonable cost. Cost-effectiveness analyses include the expected benefits and costs of interventions and can assess the value of screening tests (28, 29).

The consideration of whether to perform a test in-house or to send it to a referral laboratory is influenced by several factors (30, 31). One factor is the comparison of the estimated total cost of performing the test in-house versus the estimated total reimbursement for that test. The costs must include capital expenditure for equipment, instrument maintenance, reagents, consumables, controls, repeat testing, and personnel expenses. Expected test volume must be considered in the equation. Other issues concern the technical expertise of existing personnel, space availability in the laboratory, frequency of test performance, the time and complexity of processing the specimen for referral, and the test's clinical acceptance (i.e., likely to become commonplace or remain esoteric).

Additional factors include consideration of required turnaround time, accreditation and quality of the available reference laboratories, specimen transport issues, reporting format, and method of report delivery (computer, fax, mail, or courier). Because of variances in individual laboratories and the population or community that they serve, there will also be variances in needs for and utilization of tests among laboratories.

As noted above, reimbursement from Medicare, managed-care plans, and any third-party payors must also be considered when determining if a test is considered cost-effective or not. As utilization increases for a particular test, more accurate determination of cost-effectiveness can be made. Even though reimbursement is an important component, there are other ways to measure a test's cost-effectiveness. A test's contribution to patient care and appropriate patient outcomes also plays a crucial role. Although a test may be a financial loss, it may contribute significant savings to institutions either from a patient safety standpoint or in financial savings by other means. For example, a nonreimbursable, rapid molecular-based test of sputum that is smear positive for acid-fast bacilli can show the absence of *Mycobacterium tuberculosis*, thus forestalling the need to isolate the patient and providing a significant cost savings to the institution. Another example is the rapid, same-day diagnosis of enterovirus meningitis, precluding the need to hospitalize the patient or to begin other antiviral or antibacterial therapies, thereby saving the organization the associated costs. To recognize such financial savings to all areas within the institution, the laboratory must work closely with other clinical departments.

Test implementation: verification and validation. Before introducing any new test into the clinical laboratory, the performance characteristics of the assay must be "verified," if it is an FDA-approved or FDA-cleared test, or "validated," if it is a laboratory-developed test. Testing criteria needed for new test verification can be found under "test method validation" in Table 23.2. Some assays have gone through an FDA 510(k) clearance or PMA (premarket approval) process and are referred to as *in vitro* diagnostics or IVDs. An IVD that has gone through and passed a PMA trial is considered FDA approved. However, many new diagnostic assays (particularly molecular assays) are developed within individual clinical laboratories and are referred to as laboratory-developed tests or LDTs. Many of these clinically relevant LDTs are unlikely to become FDA cleared or approved because low test volumes make it economically unfeasible to go through the current FDA 510(k) or PMA approval process.

CLIA '88 specifies that for a newly introduced or modified test methodology a laboratory process must be in place to initially verify the test and periodically validate its performance (4, 5). This topic, including discussion of methods for verification and validation, is well reviewed elsewhere (4). Verification includes evaluation of the performance of a new or modified test being introduced into the laboratory. It focuses on the determination of new performance characteristics or confirmation of commercially determined and published performance characteristics for a test. Specifically, in verification, test sensitivity, specificity, and perhaps predictive values must be determined or confirmed. Verification results must be available for physician review during the tenure of the test method in the laboratory (4, 32). Validation, on the other hand, as a component of an ongoing laboratory quality assurance program, periodically evaluates and documents the

本书版权归John Wiley & Sons Inc.所有

performance of a test over time to ensure its continued provision of expected results established during verification. Guidelines from manufacturers and accreditation agencies may be used to determine the validation frequency for a test; CLIA '88 suggests 6-month intervals.

Appropriate Test Utilization

In the patient-oriented, cost-effective laboratory, periodic evaluation of test utilization and appropriateness of test ordering is mandatory. Inappropriate or excessive testing takes scarce laboratory resources that could be used elsewhere (8). The Joint Commission (TJC), formerly called the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), describes the foundation for laboratory responsibility for clinician education in test appropriateness. In its standards (*Accreditation Manual for Hospitals*, standard PA 1.2.7) TJC stresses that the medical director of clinical and pathologic laboratory services should ensure that an active policy for the monitoring and evaluation of the quality and appropriateness of the services provided be in place (6, 7). Because laboratory tests are a form of clinical intervention, the laboratory medical and administrative management teams have a professional and moral responsibility to clinicians to advocate for the patient (10, 33). Legal and ethical implications also dictate providing the patient with information to aid in understanding the risks and benefits of testing (14, 33).

Test evaluation. There are many examples of tests for which monitoring of testing practices is mandatory to determine appropriateness. These examples may include, but are not limited to, repetitive testing on the same specimen sites within short time periods (e.g., 24 hours), excessive numbers of cultures (e.g., more than two to four blood cultures per episode; daily sputum cultures), cultures of superficial sites (e.g., pressure ulcers), and cultures of inappropriate specimens (nasal swabs for etiologies of pneumonia). If available, technical specialists or other senior personnel in each area may encounter situations (through studies, day-to-day tracking duties, quality assurance, recently published articles, interdepartmental interactions, meetings, or other problem-solving circumstances) that indicate which tests are good candidates for further appraisal. Input from bench technologists concerning clinician-laboratory interactions, usually from telephone calls, may also be a source of potential problems suggesting additional test evaluation.

Some suggest that the Pareto principle, also known as the 80/20 rule, can be applied (27). This rule is commonly employed in many types of industry and states that 80% of an entity's total revenues are produced by 20% of its products. For the laboratory, this means first listing all tests performed by the lab and ranking them according to total annual revenues produced by each test. The NCCLS (CLSI) Approved Guideline GP11-A gives further details of using the principle, along with definitions and examples (27).

Laboratory tests may be overutilized, underutilized, or utilized incorrectly. Overutilization occurs when tests are ordered in the wrong clinical setting or too frequently; underutilization implies that relevant tests are not ordered in the right clinical circumstances. Incorrect utilization occurs when results are ignored or interpreted improperly. Increased laboratory testing does not enhance quality of patient care or ensure that there are no serious negative consequences with the reduction in testing (34). A potential problem with superfluous testing is that with a larger volume of information to read and comprehend, a clinician may overlook the more important and relevant test values. The CLSI has published a guide about laboratory utilization management programs (35), and the Patient-centered Laboratory Utilization Guidance Services (PLUGS) has published guidelines for establishing utilization efforts (36). Both emphasize the need for support from an organization's leadership and the importance of a multidisciplinary effort.

Utilization and appropriateness. Utilization and appropriateness issues are related. While utilization may have more to do with frequency of testing, appropriateness is concerned with test use for the right patient in the correct setting for the proper monitoring and for diagnostic or therapeutic reasons. Improving utilization can reduce laboratory costs while precluding several unpleasant alternatives such as rationing laboratory tests or eliminating some altogether. Several published studies illustrate possible changes by reviewing utilization and appropriateness. In 2000, Jacobs et al. questioned whether all trauma victims being admitted to the hospital required, per hospital protocol, a complete battery of 11 laboratory tests (37). Patients in the severe injury-unlikely group received only two laboratory tests, while those in the severe injury group received five. Evaluation after the 3-month study period showed no patient care problems, no change in quality of patient care, and a cost savings for the organization.

Toubert et al. assessed possible overutilization or inappropriate use of various thyroid tests within their hospital network (38). Thyroid test needs vary, whether for disease screening, diagnosis, or monitoring. In a trial period, physicians were asked to provide justification and clinical information if tests other than thyroid-stimulating hormone were ordered. With education and a requirement for justification, appropriateness of ordering was increased by approximately 30% for most tests. In the mid-1990s, Valenstein et al., working with the College of American Pathologists and 601 institutions, assessed the use of routine stool microbiology tests in the hospital setting (39). Nearly 60,000 specimens were evaluated, leading to the establishment of guidelines to limit routine bacterial stool

本书版权归John Wiley & Sons Inc.所有

cultures to the first 3 days of hospitalization. In a final example, panels of preoperative laboratory tests appeared to have high usage with low yield and little change in patient management (40). Studies at a variety of facilities led to new guidelines based on patient age and history, thus reducing automatic use of large preoperative panels while not adversely affecting patient outcome.

It has been described as very difficult, if not impossible, to change physicians' test-ordering practices (8). Physicians often have prior experience with hospital "quality" programs under various guises and may feel that, in the end, beyond "harassment" and poorly disguised cost-cutting, little has occurred to improve patient outcome. Interventions such as educational strategies, feedback, and changing test order forms may improve the efficient use of laboratory tests in primary care; however, the level of evidence is low and the quality is poor (41). For these reasons, it becomes imperative to include clinical specialists and service leaders when attempting to alter laboratory utilization patterns.

When considering utilization and appropriateness of testing, one challenge is the use of diagnostic testing to reduce the risk of malpractice liability (42). These findings suggest that physicians tolerate greater clinical uncertainty in coronary artery disease testing and treatment if they face lower malpractice risk.

Importance of communication. Through communication and the establishment of professional relationships, consensus between medical staff and laboratorians can help effect positive change. First, it is necessary to examine patterns of clinical thinking, clinical pathways, local and national peer guidelines, preferred practice patterns, and if available, clinician algorithms for decision making (8, 43). This examination can lead to the establishment of customized groupings of laboratory tests for various specialties, which can provide quality results for the lowest cost (e.g., hepatitis serology panel for acute hepatitis and Epstein-Barr virus serology panel for acute mononucleosis). Outdated tests may be eliminated, and sequential protocol testing may be developed in line with diagnostic algorithms (44). To facilitate actual change, validated best-practice information must be accepted by physicians (25). Other helpful steps include recurring meetings with medical staff committees to explain policies, new tests, or changes in protocol; publication of practice guidelines; integration of the laboratory information system (LIS) into clinician workflow; issuing handbooks (hard copy or Web based); and education by clinical leaders or respected peers. The laboratory physician may also use consultation, interpretive reporting, and cumulative laboratory reports (8). Free-texting comments may be necessary for some specific situations; however, for consistency, error-free reports, and later data retrieval, standardized (canned) comments should be created for more common reporting situations (45, 46).

Options for physician/laboratory consultation can include information centers staffed by a medical technologist, and a clinical pathologist feedback provided to family doctors as a routine healthcare activity. The overall benefit of these options is the use of thorough, consistent, and comprehensive personal feedback. Feedback is provided in a report by respected clinical specialists and concerns both overuse and rationality (in accordance with guidelines or standards). This system requires available experts to provide feedback and a requisition form that allows for basic input of patient clinical data.

Some institutions use more sophisticated software programs to assist with ordering compliance and appropriate test utilization (12). These systems use information technology to enhance clinical decision making, allowing compliance to increase reimbursement rates and timeliness in processing of orders. These software programs are continually evolving as new procedures become available, as professional guidelines are updated, and as the users provide feedback.

House staff physicians support a unique environment for influencing and training in optimal test ordering. Clinical service leaders, in cooperation with the laboratory, can track frequency and volume of testing by residents and use this as an instructive tool (8). Education, peer review, and feedback were most helpful in combination for improving staff test utilization. Information included test costs, as well as individual resident results tracking the numbers of tests per patient.

Pharmacists and infection control personnel play a role in selecting or recommending laboratory tests as well and, when appropriate, should be consulted by the laboratory for input (47, 48). Not only may they order or recommend laboratory tests pursuant to consult with a clinician, but they also need to interpret and apply test results when making recommendations concerning therapy or isolation precautions. Their role as intermediaries between the laboratory and clinicians should be used for any applicable evaluations or studies.

The information technology department can also be a great asset in influencing ordering practices. Algorithms can be applied to influence ordering of tests or in tracking utilization. Schubart et al. studied the use of algorithm-based decision rules to employ appropriate intervals for repeat testing for some commonly ordered laboratory tests. For example, for serum potassium testing in their hospital, application of the established algorithm allowed for a 34% reduction in testing for the first 5 days of hospitalization without a reduction in quality of care (49).

Even a model laboratory compliance plan can assist in controlling redundant testing (50). With the passage of the Health Insurance Portability and Accountability Act of

本书版权归John Wiley & Sons Inc.所有

1996 (HIPAA), and later the Medicare Integrity Program, laboratory managers may now have legal liability for inappropriate test utilization. The development of an institution's individual compliance plan is an occasion to incorporate processes for tracking utilization and making appropriate changes. The most successful plans should define the roles of various departments in compliance monitoring and tie the hospital laboratory to the compliance office, usually with the use of the LIS. Commonly, LIS records can show test usage rates and patterns. Meetings with the nursing, physician, or other staff involved are recommended as follow-up to potential compliance problems.

The federal government mandated that electronic medical records (EMRs) be implemented by 2014 and offered incentives, in the form of both rewards and penalties, to help drive their adoption by physicians and health organizations. The American Recovery and Reinvestment Act was legislated to provide a network of incentives that could be directly resourced toward healthcare professionals or physicians for adoption of EMRs by 2014. Support for EMRs is based on the advantages they provide: benefits of securing patient information and lowering healthcare costs. Such records can be used rapidly to monitor utilization and to correlate it to increased or decreased good patient outcomes, thereby affecting patient management strategies.

Specimen Acquisition, Transport, and Storage

Requisition information. There has been a tendency in today's medical climate to place more emphasis on primary care clinicians seeing more patients and fewer referrals to the specialists or subspecialists. Often, this emphasis encourages the use of more diagnostic tests to ensure high-quality patient care, but decreases the time allocated to evaluate the patient or to research diagnostic test ramifications. One of the laboratory's primary responsibilities is to ensure that adequate information is provided to the clinician-client to make appropriate choices in specimen collection and test ordering. CLIA regulations state that the laboratory must establish and follow written policies and procedures characterizing and describing each of the following, when applicable:

- Patient preparation
- Specimen collection (routine versus STAT)
- Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source (some cases require more information; can be modified as required)
- Specimen storage and preservation
- Conditions for specimen transportation
- Specimen processing

BORDETELLA CULTURE
(WHOOPING COUGH) [Includes *B. pertussis* and *B. parapertussis*]
Specimen: Submit 2 nasopharyngeal swabs in Regan-Lowe transport medium. Specimens should be stored refrigerated until and during transport to the laboratory. Other transport media are not suitable for maintaining the viability of pertussis organisms.
Method: Conventional Culture
Setup: Monday through Sunday
Available: Negatives 7 Days
CPT: 87081
Reference Ranges: None Isolated
Note: Cultures are not useful in adults. Serologies or PCR studies should be considered. All positives are called upon isolation.
Collection: Use a mini-tipped culturette to collect 2 nasopharyngeal swabs. The swab is gently inserted through the nose to the posterior nasopharynx where it is gently rotated. It should remain in this position for several seconds. The withdrawal should be slow to minimize irritation. Place in Regan-Lowe transport medium. Specimens should be stored refrigerated (2–8°C) until and during transport to the laboratory.

Figure 23.1 An example of information and instructions in a laboratory users' manual for collection and submission of specimens for evaluation of whooping cough.

- Specimen acceptability and rejection
- Specimen referral
- Specimen reporting timelines

For each test offered, the laboratory must be able to provide the appropriate collection materials and instructions together with adequate transport systems and suitable equipment to process and/or store the specimen (Fig. 23.1) (29). Additionally, the laboratory must document the date and time of receipt of the patient's specimen.

Specimen transfer to reference laboratory. When a specimen requires transfer to a reference laboratory, it is the submitting laboratory's responsibility to ensure that the reference laboratory receiving the specimen is either CLIA-certified or meets equivalent requirements as determined by CMS (15). When tests are to be referred to another laboratory, all pertinent information should still be provided to the clinician, including the destination of the referred specimen. Written instructions should be available for the client to be able to get additional assistance for unusual circumstances or special specimen handling situations. Instructions and testing schedules can be obtained from manuals published by the individual reference laboratories.

Mechanisms for problem identification and resolution. For quality assessment and performance improvement,

本书版权归John Wiley & Sons Inc.所有

the laboratory must establish and follow written policies for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytical testing phase. The preanalytical systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems assessment reviews with appropriate staff. Furthermore, the laboratory must also document all preanalytic systems assessment activities as well as its attempts to modify clinicians' ordering patterns or behavior when consistent problems in specimen submission occur.

Test Ordering

Test requests may be received in a variety of ways but must be in either written or electronic form and must originate from an authorized person. Such authorization is prescribed by state law and may vary from state to state. The laboratory should encourage the clinicians to specifically write in the orders for any add-ons they decide on at the last minute. Oral requests for laboratory tests are acceptable if followed within 30 days by written orders (5). The laboratory must document its attempts to obtain written authorization in cases where oral requests are not followed by written ones in a timely fashion.

A detailed test requisition enables the laboratorian to provide a higher caliber of service to the physician and patient. Timely, accurate, and relevant results are attained with a comprehensive requisition form. Additionally, proper reimbursement is more likely to occur with this type of form. The form must be easy for the client to complete and must contain all pertinent information necessary for proper result interpretation. Phone calls to verify any missing or vague data severely consume resources from both the laboratory and physician's viewpoint. Therefore, a considerable amount of time should be spent on developing a requisition format and educating clients in its usage.

Electronic test requests. Electronic requests are frequently utilized in hospital settings where the laboratory information system (LIS) connects with either handheld devices or stationary terminals that the medical staff uses to order tests. Electronic test ordering systems are becoming more common, even in off-site locations and clinics, and in many instances can be designed to help guide physician test order choices. Such formats can include "caresets" for specific diagnoses, which list the appropriate tests first and leave out the less desirable ones. The conventional manually printed multicopy paper request form may still be common in some facilities, such as clinics or clinician offices, or when sending tests from one facility to another; however, with today's connectivity, electronic requests continue to gain popularity. Often, a physician will handwrite the desired tests on a prescription pad (script) rather than use a requisition. Such a practice should be discouraged, as multipart requisitions or electronic orders are preferred to scripts for a multitude of reasons. In any laboratory setting, it is imperative to possess a down-time procedure for occasions when the standard operating procedure cannot be followed, such as with electrical or computer outages.

Test requisition. Typically, a written or electronic requisition consists of a demographics section and a test selection section. The general information needed for the demographic section of a test requisition is depicted in Table 23.8. If the laboratory transcribes or enters test requisition or authorization information into a record system or an LIS, the laboratory must ensure that the information is transcribed or entered accurately. Requisitions must include two unique identifiers such as the patient's name and medical record number, as well as the name and address of the person authorized to request the test (5). It is also recommended that a contact person and phone number be listed in case additional information is required or when critical values require immediate notification.

All applicable diagnosis codes for the date of service should be specified on the requisition. Diagnosis codes are typically referred to as International Classification of Disease (ICD) codes, which are published by the World Health Organization. These codes not only help interpret results but may also be required for reimbursement by third-party payors.

The evaluation of specimen stability depends on the date and time of specimen collection. Some demographics, such as the patient's sex, date of birth, and fasting state, may affect patient reference ranges in certain procedures. This information also ensures accurate patient

Table 23.8 Demographic information needed on test requisition[a]

Authorized person ordering test
Individual using test results (when appropriate)
Laboratory submitting specimen (with contact person for STAT tests)
Patient name or unique identifier
Patient sex and age (or date of birth)
Source of specimen (if appropriate)
Time and date of collection of the specimen (as needed)
Patient's last menstrual period and indication of whether patient had a previous abnormal report, treatment, or biopsy (for PAP smears only)
Additional information that may be needed for specific tests to ensure timely, accurate testing and reporting (with appropriate interpretation)

[a] See reference 5.

本书版权归John Wiley & Sons Inc.所有

identification for appropriate billing and charting of laboratory tests.

The billing information required depends on how the client has the account set up with the laboratory. The laboratory can bill the patient, a third-party payor, or the client (the client can then bill the patient or his or her insurance provider), or a combination of payors. Thus, the patient's Social Security number, home address, and phone number may not be required if billing the client. Similarly, insurance information may not be necessary. Laboratories often print the most common tests and their test codes in the test-request section of the requisition for user convenience. Not only specific tests, but test panels can be preprinted on the requisition. However, due to compliance issues, it is the responsibility of the laboratory to educate the client that, although there is a panel or test preprinted on the form, the option to order any panel or component separately is still available.

The test selection section should include an area to indicate the specimen site or source. This is especially true when handling anatomic pathology or microbiology specimens. In such situations it is also imperative to know the type of procedure that was performed and the nature of the disease. For PAP smear testing, CLIA '88 requires inclusion of the date of patient's last menstrual period, age or date of birth, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.

Other information that should be included on a test requisition includes notation of any medications the patient may be on, symptoms or suspected diagnosis or organism, antibiotic allergies (where pertinent), priority of testing (e.g., STAT), and copy-to instructions for additional reports where needed.

Advanced beneficiary notice. The CMS developed a new advanced beneficiary notice (ABN) form in 2002. The new ABN is intended to provide a standardized form that results in more effective communication to beneficiaries. For limited-coverage laboratory tests that Medicare is expected to deny, an ABN form must accompany the test request. Patients have the option to ask for an estimated cost and may decline testing if they choose (which is documented on the ABN). An ABN does not take the place of a test requisition (51).

Local Medicare carriers disseminate specific instructions on when and how to order screening tests. If these specific tests are ordered more often than is medically necessary as indicated by CMS guidelines, the beneficiary may be held responsible for payment. However, the same test that is used for screening purposes may also be used as a diagnostic tool if specific symptoms or diseases are present. Medicare will cover this testing when the diagnosis codes provided support the necessity requirements.

Postanalytic Activities

The postanalytic phase refers to all steps taken after actual testing is performed on a patient's specimen. It includes the reporting of test results, report review, result archiving, and specimen storage, as well as assessment of all postanalytic activities (Table 23.9).

The Report

Although the laboratory should release results only to authorized people or the individual responsible for utilizing the test results, some state regulations allow reporting directly to patients (52, 53). The reports can be sent through a variety of means, including verbal, written, or electronic. Clear processes must be in place to allow timely reporting of preliminary, interim, or final reports. Written procedures for reporting of results exceeding normal values (STAT or critical) must be published and clearly understood and followed by laboratory personnel. Any such reporting must have documentation of when, where, to whom, and what was reported.

Report turnaround time. The caregiver should have available the expected turnaround time (TAT) for a report to be generated from the time the specimen is collected. It is the laboratory's responsibility not only to make available the TAT information for all tests, but to periodically monitor TAT to determine that reports are being sent without excessive delay and that there are no problems in the process. When excessive TAT is confirmed, corrective action (CA) must be initiated, and all steps in the CA process must be documented. If any delay occurs beyond the expected TAT for any test, the laboratory must have a process in place to notify the clinician of the status of the specimen.

Types of reports. The main means used for reporting laboratory results are EMR, Web-based reports, and

Table 23.9 Areas that should be reviewed or evaluated in quality assessment of postanalytic systems[a]

Effectiveness of corrective actions
Procedures and policies to prevent recurrences
Accuracy and completeness of test results and reports
Disposition of unacceptable specimens
Turnaround times
Referral specimens and their reports
Corrected reports
Procedures for notification of test results, including for STAT situations
For analyte-specific reagents, test reports should include information necessary for proper interpretation of results, including disclaimers as needed.
Ensure confidentiality of patient information

[a] See references 5 and 13.

本书版权归John Wiley & Sons Inc.所有

standard paper reports. Although somewhat infrequently used now, paper reports will likely survive for a time as backup systems in the event of electric or computer downtime. With the EMR, laboratory data are transmitted to a hospital information system and are integrated with patient demographic information, providing integrated reports for in-house patients. When available, Web-based reports have the advantage of multiple access points, and clinicians can access them from any internet connection. Web-based and EMR reports must be validated initially and periodically to verify that the information transmitted is being translated accurately and in the approved format. Ultimately, regardless of how many or what types of computer systems or networks results travel through, the laboratory must ensure that results get to the authorized person who will act on the results in an accurate and timely manner.

Results format. The standard test report must include the name and address of the laboratory at which the test was performed, the test that was performed, the test results (including the unit of measurement, if applicable), any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability, as well as the laboratory's reference or normal ranges for specific tests, if applicable. If the latter is not included on the report, it must be available to the authorized person who ordered the test or to the person responsible for utilizing the test results.

It is also the responsibility of the laboratory to make available to clients a list of test methodologies, including any information regarding interpretation of test results. Any changes to this testing information that would affect results or interpretation of results must be communicated to physicians. For tests using analyte-specific reagents or test systems not FDA approved for use on patients, disclaimers reflecting such status must be added to reports. The disclaimer statement may read, "This test was performed using a kit that has not been cleared or approved by the FDA. Performance characteristics of this test have been determined by (laboratory name). This test should not be used for diagnosis without confirmation by other medically established means." The FDA has further clarified that testing systems labeled by manufacturers as being for "research use only" should not be used for decisions in actual patient care, and reports based on such testing should have the appropriate disclaimer attached; testing performed for "research" purposes is not reimbursable by Medicare. Additional "value-added" textual comments can be added to reports to help the clinician interpret results or to better understand how to use the results appropriately (Fig. 23.2) (3). Although free texting allows greater flexibility in comment writing, it also provides a greater potential for errors and a lack of standardization of responses to specific, commonly encountered situations. Thus, predetermined (canned) and standardized comments are preferred in such cases.

The reports should be easy to read, unambiguous, and readily interpretable and should use standard terminologies. Studies on a variety of surgical pathology reports found that subtle nuances in wording of the diagnosis and comment lines could be significant if misinterpreted (54). They stressed using redundancy (restating what might seem obvious) and avoiding certain ambiguous words.

Quality assessment and corrected reports. The laboratory must have a process in place to monitor and evaluate its test results and reports for inconsistencies and inaccuracies. Such evaluation must include a review of patient test reports for completeness of patient information, accuracy of test results, normal ranges, and correlation between test results; validation of LIS reports to verify accurate transmission and/or transcription; and review of corrected reports (5). There must be a mechanism for correcting an erroneous report and identifying the new report as one that is corrected while maintaining both reports in the patient's record.

Storage and Retention

Regulatory constraints require that the laboratory have processes and procedures for the retention and storage of specimens and records. Storage regulations may differ between various agencies (Table 23.10). Individual state laws are typically more stringent than those of the federal government or other agencies. In any case, the laboratory should follow the more stringent regulations, which should be reviewed periodically to ensure they are current.

Specimens. A sample list of specimens that must be stored is given in Table 23.10 (2). A procedure should be in place for their retention based on the most stringent regulatory requirements for the individual laboratory.

Records. Typically test requisitions and reports must be stored in a retrievable fashion for a minimum of 2 years. Some records, especially in areas of immunohematology (5 years), histocompatibility (5 years), histology (10 years), cytology (10 years), bone marrow (10 years), and cytogenetics (25 years), may require longer retention periods (2). In this litigious era, many laboratories are opting to hold records and documents for longer periods of time. Record retention is made easier if electronic copies are used.

Assessment of Test Results on Patient Outcomes

Outcome analysis. The science of outcome analysis has been in common use by physician, nursing, and pharmacy staffs for many years. However, only recently has it gained importance in the laboratory as regulatory agencies focus

本书版权归John Wiley & Sons Inc.所有

MICROBIOLOGY/INFECTIOUS DISEASES

- Coagulase positive staphylococci are rare causes of primary UTI. In the absence of catheterization, such infections may originate via hematogenous dissemination from another source.
- Methicillin (penicillinase-R-penicillin) resistance in *Staphylococcus* species infers resistance to all other penicillins, beta-lactamase inhibitor combinations, cephalosporins and carbapenems.
- A characteristic of the *Streptococcus anginosus* group is its frequent association with abscesses. When these organisms are isolated from the blood, the possible presence of an abscess should be considered.
- Presence of this organism at this site is not indicative of its role as a cause or contribution in an infectious process, and may not require specific therapy.
- *Plasmodium* spp. seen: Unable to rule out *Plasmodium falciparum* or *P. knowlesi*.
- *Entamoeba histolytica*/*E. dispar*: Differentiation between the pathogen *E. histolytica* and the nonpathogen *E. dispar* not possible based on organism morphology.

SEROLOGY/IMMUNOLOGY

- Antibodies to cardiolipin have been found in a subgroup of patients with autoimmune disorders as well as in some patients with myocardial infarction and acute and other infections, including syphilis and AIDS.
- IgG and IgA cardiolipin antibodies have been associated with thrombocytopenia, arterial and venous thrombosis and recurrent fetal loss with the predictive value and specificity increasing with the level of cardiolipin antibodies.
- IgM cardiolipin antibody is predominately found in association with infections unless a lupus anticoagulant is also present.

CHEMISTRY

- In addition to congenital Protein C deficiency, decreased Protein C activity can be seen in association with Vitamin K deficiency, severe liver disease, nephrotic syndrome, disseminated intravascular coagulation and other disease states where consumption is increased. Decreased Protein C activity is also seen in patients on Warfarin therapy or oral contraceptives.
- A low ratio is indicative of activated protein C resistance due to a factor V gene mutation. This could be confirmed by ordering a Factor V Leiden (PCR) assay. Note that the presence of inhibitor activity (e.g. phospholipid antibodies or a specific factor inhibitor) may cause an abnormal APCR result.
- Specimen is grossly hemolyzed. The following results may be affected: increase in glucose, potassium, ALT, AST and total bilirubin; decrease in alkaline phospatase. Suggest recollection if clinically warranted.

URINALYSIS

- Color interference noted- may affect the result of the dip stick tests.
- Unable to read due to color of urine.

HEMATOLOGY

- Analyzer counts may be inaccurate due to platelet clumping; suggest redrawing in citrate tube.
- Platelets clumped on smear, invalidating results.

COAGULATION

- Proteins C and S results may be falsely decreased due to coumadin therapy.
- Specimen is hemolyzed and may cause shortened PT and APTT results. Evaluate results with extreme caution.
- Findings suggest the presence of a platelet autoantibody. Recommend obtaining a direct platelet antibody test for confirmation.

Figure 23.2 Sample list of textual "value-added" comments attached to specific laboratory reports.

on laboratory-associated patient safety and outcome issues (55). In its 1996 *Comprehensive Accreditation Manual for Pathology and Laboratory Services*, TJC defines quality to include outcomes: "the degree to which patient care services increase the probability of desired patient outcomes and reduce the probability of undesired outcomes, given the current state of knowledge" (7). More recently, the Affordable Care Act has elevated the importance of outcomes by focusing on their application to payment by CMS, with organizations being either rewarded or penalized depending on the outcomes in their patient populations. The concept of accountable care organizations (ACOs), with single payments for the overall medical care of individual patients over time, has further increased the importance of measuring outcomes to implement strategies to improve care.

Measurable outcomes. Generally, measurable outcomes are defined in two areas: clinical and financial. Clinical patient outcomes, because of medical care, relate to the patient's functional status, health status, and quality of life (21). Measures that are often used for outcomes are familiar to those in the hospital setting: length of stay, mortality, morbidity, infection rate, complication rate, readmission rate, and others. Case management and quality management departments are good sources of quality

本书版权归John Wiley & Sons Inc.所有

Table 23.10 Example of specimen retention requirements by regulatory agency[a]

	Retention period required by:		
Specimen	**CAP**	**CLIA**	**TJC**
Body fluids, CSF, serum	24 hours		
Bone marrow smears	10 years	20 years	
Fine-needle aspirates	10 years		
Histology slides			10 years
Negative or unsatisfactory cytology slides	5 years	5 years	5 years
Normal blood films, body fluid slides	7 days		
Paraffin blocks	10 years	2 years	2 years
Positive/questionable cytology slides	5 years	10 years	5 years
Wet and formalin-fixed tissue	2 weeks		7 days

[a] See references 5 and 13.

indicators and measures of performance typically used across institutions and within their statistical analyses. Financial outcomes may concern costs to the patient, a particular department within the healthcare institution, the institution itself, the insurer, or even society at large. One author suggested that all tests offered by the laboratory need clinical trials with outcome result studies to show whether they are valid or not (56). Such studies become even more relevant with the focus on population health management, on chronic disease, and on preventive care and wellness with the potential growth of ACOs.

Outcome studies. Outcome studies may take a narrower perspective in the laboratory. In simpler terms, the question may be posed, "When the laboratory reports a specific result for a specific patient for a particular test reported in a specific way, what is the clinician response and subsequent change (if any) in patient management?" Actions taken from the more limited focus will, of course, influence the larger measures described above. It may be said that the only true assessment of the quality of laboratory testing is reflected by the quality of patient outcomes (57). The laboratory must be recognized as playing an integral role in patient management rather than be viewed as an "ancillary" department. The clinical laboratory's contributory role is already crucial in antimicrobial stewardship programs and in prevention of hospital- or healthcare facility–acquired infections. Ultimately, various studies may lead to new roles for the clinical laboratory (21). Such roles should include expansion of direct participation in patient care and in contribution to clinical care consensus groups.

As with test evaluation, ideas for outcome studies may arise from technical coordinators, technical specialists, clinical laboratory scientists (bench technologists), technical directors, or laboratory/department directors. They may be pursuant to articles read in the literature or discoveries made during an annual budget review or after discussion with a clinician or other staff member. Many good studies focus on a targeted clinical service, such as pharmacy (34, 55, 58). A multidiscipline team is usually needed to gather all necessary information and complete the analysis. The team may include, as needed, but is not limited to, nursing, pharmacy, case management, laboratory, epidemiology or infection control, clinical specialists, statisticians, information technology, medical records, and finance and legal departments. Data may be derived from medical records, LIS, pharmacy information system, billing/charge databases, patient account databases, quality improvement studies, and satisfaction survey systems. Generally, information systems are used as well in radiology, respiratory care, dietary, operating room, and other departments and can provide valuable information for studies.

For example, in a published study, Barenfanger et al. sought to examine the impact of a program used to improve interventions involving antibiotic therapy (34, 58). The manual, paper-based method of pharmacy review was compared with a system using a computer software program that linked immediately to the pharmacy in cases of alerts for possible intervention. Alerts could show patients with a bacterial isolate and no order for antimicrobial therapy, patients with a bacterial isolate resistant to their current therapy, patients receiving a therapy not tested, or patients with no cultures collected but who were receiving antimicrobial therapy. For the group of patients with alerts generated by the computer software program, the physician received more rapid notification of the information in the intervention. Analysis showed that this group had significant differences in lengths of stay, total costs, variable costs, and radiology costs.

Other institutions have had success with comparable programs (59, 60). Some laboratories may have sophisticated algorithms available to search for, among other situations, suboptimal therapy, or use of intravenous antimicrobials when an oral agent might be substituted. This system and others can provide savings by keeping antimicrobial costs down but, more importantly, have been shown to reduce length of stay, days of intubation, number of subsequent laboratory and radiology tests, and days in intensive care for many patients (16). In almost all instances, multidisciplinary teams oversee interference or outcome evaluation programs.

In a second example, Kollef et al. worked with the microbiology department in a study involving ICU patients who were mechanically ventilated (61). Ventilator-associated pneumonia (VAP) can be a significant factor in the mortality of critically ill patients. By collecting mini-BAL (bronchoalveolar lavage) cultures, the researchers hoped to determine the best strategies for administration of antibiotics to improve outcomes of the patients with

本书版权归John Wiley & Sons Inc.所有

VAP. From their data, they were able to confirm the findings of earlier investigators and develop recommendations for the empiric treatment of VAP.

The College of American Pathologists has developed a series of patient outcome templates—education-based information tool sets to assist member pathologists in setting up outcome measurement studies at their institutions (62). Each template set contains several modules: a set of text pages reviewing a particular disease; references; a table of applicable indicators for outcome measures; and a PowerPoint presentation with tables, charts, and cost-saving models. For example, one template works with the underutilization of lipid analysis in identifying patients at risk for coronary artery disease. Additional tools such as these templates will be emerging as laboratories become more routinely involved in patient outcomes.

SUMMARY

The clinical laboratory has an expanding role in today's healthcare setting. It must, first and foremost, provide accurate and timely, quality-minded, appropriate analytical testing to help clinicians diagnose and manage medical conditions in patients. It must also recognize its responsibility to provide the overall guidance for appropriate test utilization and result interpretation and to assess the impact of its results on patient outcomes. As such, the laboratory continues to expand its role as a team player and participant in overall patient management. To fulfill its role adequately, the laboratory must outline, measure, and document the processes needed for all phases of work performed; it must be especially cognizant of the crucial role of preanalytic and postanalytic activities in the provision and application of its accurate, quality-assured, and cost-effective end products. Laboratory professionals must provide services that help physicians focus their test selection. They must also convey and connect the importance of patient preparation and identification with patient safety and improved outcomes to all levels of care givers. Clinical laboratory professionals will need to explain, interpret, and relate results to patient care and outcomes. As laboratory professionals extend their expertise and attention to the pre- and postanalytical phases of their services, one may see improved quality of laboratory testing.

KEY POINTS

- Preanalytic activities include, but are not limited to, test selection, implementation, appropriate utilization, and ordering, as well as specimen collection, transport, and storage.
- Postanalytic activities include, but are not limited to, reporting of results, storage and retention of specimens and information, and assessment of the effect of test results on patient outcomes.
- Preanalytic and postanalytic activities are crucial to accurate laboratory results and to their appropriate interpretation for patient care.
- Effective laboratory test menu nomenclature, formats, and comprehensive listing enhance appropriate test ordering.
- Adequate explanation and interpretation comments related to result reports are important and can greatly influence patient care and outcomes.
- The role of the clinical laboratory includes assessment of the effect of its results on patient care and outcomes.

GLOSSARY

Accountable care organization (ACO) A healthcare organization characterized by a payment and care delivery model that seeks to tie provider reimbursements to quality metrics and reductions in the total cost of care for an assigned population of patients.

Affordable Care Act (ACA, 2010) A series of reforms to health insurance designed to increase the availability of health insurance policies to individuals.

Analytic activity Pertaining to actual performance of a test procedure on a specimen.

Analyte-specific reagents Defined by the FDA as "antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended to use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens." (21 CFR 864.4020)

Centers for Medicare and Medicaid Services (CMS) Primary federal body responsible for the oversight of clinical laboratory activity and licensure. In the United States, the CMS regulates all nonresearch laboratory testing performed on humans through the Clinical Laboratory Improvement Amendments (CLIA).

Clinical and Laboratory Standards Institute (CLSI) The CLSI (formerly National Committee for Clinical Laboratory Standards, NCCLS) is a not-for-profit organization that develops laboratory standards worldwide.

Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) Passed by Congress in 1988 to establish quality standards for laboratory testing and to ensure the accuracy, reliability, and timeliness of patient test results. Laboratory tests are categorized as being waived, moderate complexity, or high complexity. Laboratories performing tests in the latter two categories have to register and comply with a set of regulatory rules to become certified (licensed). In 2003, a final rule was issued in the *Federal Register* that defined some new regulations and changed the categorization of tests into two categories (waived and nonwaived tests).

本书版权归John Wiley & Sons Inc.所有

Clinical laboratory scientist The title designation for individuals who perform laboratory testing on patient specimens.

Current procedural terminology code (CPT) Test codes recognized by the American Medical Association and required for filing claims and billing to Medicare.

Direct access testing (DAT) Generally defined as consumer- (as opposed to physician-) initiated testing of human specimens. DAT is also known as direct-to-consumer or patient-authorized testing.

Electronic medical record (EMR) A medical record in digital format.

Food and Drug Administration (FDA) Federal agency responsible for the oversight of commercial tests and for their approval and licensure for use in clinical health laboratories.

Health Insurance Portability and Accountability Act (HIPAA) The U.S. Department of Health and Human Services issued the Privacy Rule to implement the requirement of the Health Insurance Portability and Accountability Act of 1996.

International Classification of Diseases (ICD) A healthcare classification system that provides codes to classify diseases and a wide variety of signs, symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or disease.

***In vitro* diagnostics (IVD)** *In vitro* diagnostics are tests done on samples such as blood or tissue that have been taken from the human body. *In vitro* diagnostics can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

Laboratory-developed tests (LDTs) Laboratory-developed tests are a class of *in vitro* diagnostic device that is designed, manufactured, and used within a single laboratory.

Logical Observation Identifiers Names and Codes (LOINC) LOINC is a common language (set of identifiers, names, and codes) for identifying health measurements, observations, and documents.

Negative predictive value Probability that a negative result indicates absence of disease or analyte.

Pareto principle (80/20 rule) Used in many industries, it states that 80% of an entity's total revenues are produced by 20% of its products.

Path of workflow Combined sequential activities in the laboratory, beginning with a clinician's ability to order a test and culminating in data being generated and reported for use in patient care.

Patient-centered Laboratory Utilization Guidance Services (PLUGS) Published guidelines for establishing utilization efforts.

Positive predictive value Probability that a positive result indicates presence of disease or analyte.

Postanalytic activity Pertains to the period after the actual testing of a specimen and includes phases such as reporting of results, storage and retention of specimens and data, and assessment of effect of results on patient outcomes.

Preanalytic activity Pertains to the period prior to actual testing of a specimen and includes phases such as test selection and implementation, appropriate test utilization, and specimen collection, transport, and storage, as well as test ordering.

Premarket approval (PMA) A premarket approval application is a scientific, regulatory documentation to FDA to demonstrate the safety and effectiveness of a Class III device.

Procedure/protocol A prescribed way to carry out a diagnostic test or other activity.

Process Systematic course of definitive actions or activities culminating in a desired end product.

Research Use Only A product that is not FDA approved for general diagnostic purposes and is labeled by the manufacturer for testing in the initial research phase of product development.

Sensitivity The ability of a test to detect a condition (number with condition testing positive / number having the condition × 100 = percent sensitivity).

Specificity Ability of a test to define a true condition (number without condition testing negative / total number without condition × 100 = percent specificity).

Systematized Nomenclature of Medicine—Clinical Terms (SNOMED-CT) A standardized, multilingual vocabulary of clinical terminology that is used by physicians and other healthcare providers for the electronic exchange of clinical health information.

Turnaround time (TAT) Turnaround time is the time, whether in hours or days, between when a sample or specimen is received at the laboratory and the time when testing is complete and results are established and released.

Ventilator-associated pneumonia (VAP) Ventilator-associated pneumonia is a lung infection that develops in a person who is on a ventilator. A ventilator is a machine that is used to help a patient breathe by giving oxygen through a tube placed in a patient's mouth or nose, or through a hole in the front of the neck.

ACKNOWLEDGMENTS

The authors would like to thank Adarsh K. Khalsa, Michael Santa Cruz, and Michael A. Saubolle for their previous contributions.

REFERENCES

1. **American Society for Clinical Laboratory Science**. 2021. Consumer direct access to laboratory testing (classification position paper). https://ascls.org/direct-access-testing-2021/. Accessed 28 July 2023.

2. **Clinical and Laboratory Standards Institute**. 2011. Quality management system: a model for laboratory services. Approved guideline GP26-A4. 4th ed. CLSI, Wayne, PA.

3. **Marcon MJ**. 2003. "Value-added" reporting in clinical microbiology: using computer-based textual reports and comments as an aid

本书版权归John Wiley & Sons Inc.所有

to communicating appropriate utilization and application of test results. *Clin Microbiol Newsl* **25**:25–31.

4. Clark RB, et al. 2009. Cumitech 31A, Verification and validation of procedures in the clinical microbiology laboratory. Coordinating ed, Sharp SE. ASM Press, Washington, DC.

5. Health Care Financing Administration. 1992. Medicare, Medicaid and CLIA programs; regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA)—HCFA. Final rule with comment period. *Fed Regist* **57**:7002–7186.

6. Joint Commission on Accreditation of Healthcare Organizations. 1990. *Accreditation Manual of Hospitals*, p 137–138. Joint Commission on Accreditation of Healthcare Organizations, Chicago, IL.

7. Joint Commission on Accreditation of Healthcare Organizations. 1996. *Comprehensive Accreditation Manual for Pathology and Laboratory Services*. Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, IL.

8. Travers EM, **McClatchey KD**. 2002. Basic laboratory management, p 3–48. *In* McClatchey KD (ed), *Clinical Laboratory Medicine*, 2nd ed. Lippincott Williams & Wilkins, Philadelphia, PA.

9. Travers EM. 2002. Business management of the clinical laboratory, p 49–77. *In* McClatchey KD (ed), *Clinical Laboratory Medicine*, 2nd ed. Lippincott Williams & Wilkins, Philadelphia, PA.

10. Linehan BJ, **El-Nageh MM**, **Cordner S**, **Richter A**. 2002. Ethics in laboratory medicine, p 134–142. *In* McClatchey KD (ed), *Clinical Laboratory Medicine*, 2nd ed. Lippincott Williams & Wilkins, Philadelphia, PA.

11. Bachner P. 2014. Anniversary of Q-Probes and Q-Tracks quality assurance programs. *Arch Pathol Lab Med* **138**:1139–1140.

12. Hawkins HH, **Hankins RW**, **Johnson E**. 1999. A computerized physician order entry system for the promotion of ordering compliance and appropriate test utilization. *J Healthc Inf Manag* **13**:63–72.

13. Centers for Disease Control and Prevention (CDC),Centers for Medicare & Medicaid Services (CMS). 2003. Medicare, Medicaid, and CLIA programs; laboratory requirements relating to quality systems and certain personnel qualifications. Final rule. *Fed Regist* **68**:3639–3714.

14. Fischbach F. 2000. *A Manual of Laboratory and Diagnostic Tests*, 6th ed, p 1–33. Lippincott Williams & Wilkins, Philadelphia, PA.

15. Howanitz JH, **Howanitz PJ**. 1991. Principles of laboratory medicine, p 1–10. *In* Howanitz JH, Howanitz PJ (ed), *Laboratory Medicine: Test Selection and Interpretation*. Churchill Livingston Inc, New York, NY.

16. Bailey MK, **Blacklidge L**, **Day CM**, **Garcia LS**, **Parks D**, **Street T**. 1995. How to curb physicians' excessive testing. *Med Lab Obs* **27**:69.

17. Sadowski BW, **Lane AB**, **Wood SM**, **Robinson SL**, **Kim CH**. 2017. High-value, cost-conscious care: iterative systems-based interventions to reduce unnecessary laboratory testing. *AJM* **130**:1112.E1–1112.E7.

18. Labeau KM, **Simon M**, **Steindel SJ**. 2001. Clinical laboratory test menu changes in the Pacific Northwest: an evaluation of the dynamics of change. *Clin Leadersh Manag Rev* **15**:16–22.

19. Nicoll CD, **Pignone M**. 2002. Diagnostic testing and medical decision making, p. 1669–1680. *In* Tierney LM Jr, McPhee SJ, Papadakis MA (ed), *Current Medical Diagnosis & Treatment*, 41st ed. Lange Medical Books/McGraw Hill, New York, NY.

20. American College of Obstetricians and Gynecologists. 2021. Group B Strep and pregnancy. https://www.acog.org/womens-health/faqs/group-b-strep-and-pregnancy. Accessed 12 October 2022.

21. Bissell MG. 2000. Introduction: what's in a laboratory outcome? p 3–10. *In* Bissell MG (ed), *Laboratory-Related Measures of Patient Outcomes: An Introduction*. American Association for Clinical Chemistry Press, Washington, DC.

22. Centers for Medicare and Medicaid Services. 2019. Direct access testing (DAT) and the Clinical Laboratory Improvement Amendments (CLIA) regulations. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/directaccesstestingpdf.pdf. Accessed 10 October 2022.

23. ASCLS. 2023. Consumer direct access to laboratory testing. The American Society for Clinical Laboratory Science, Reston, VA. https://ascls.org/direct-access-testing-2021/. Accessed 10 October 2022.

24. Garcia LS, **Procop GW**, **Roberts GD**, **Thomson RB**. 1998. Selection of diagnostic tests, p 60–63. *In* Forbes BA, Sahm DF, Weissfeld AS (ed), *Bailey & Scott's Diagnostic Microbiology*. Mosby, Inc, St. Louis, MO.

25. Leeflang MMG, **Allerberger F**. 2019. How to: evaluate a diagnostic test. *Clin Microbiol Infect* **25**:54–59.

26. United HealthCare Medicare Advantage. 2023. Policy Guideline: Molecular diagnostic infectious disease testing. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medadv-guidelines/m/molecular-diagnostic-infectious-disease-testing.pdf. Accessed 12 October 2022.

27. NCCLS. 1998. Basic cost accounting for clinical services. Approved guideline. NCCLS document GP11-A. NCCLS, Wayne, PA.

28. Statland BE. 1994. Cost/benefit of screening. *Med Lab Obs* **26**:11.

29. Iragorri N, **Spackman E**. 2018. Assessing the value of screening tools: reviewing the challenges and opportunities of cost-effectiveness analysis. *Public Health Rev* **39**:17–44.

30. Lewandrowski K, **MacMillan D**. 2003. Selection of a clinical reference laboratory: general principles and some observations from Massachusetts General Hospital. *Clin Microbiol Newsl* **25**:33–37.

31. Zhang YV. 2015. Should we bring this test in house? *AACC Clinical Laboratory News*. June, 2015.

32. Halling KC, **Schrijver I**, **Persons DL**. 2012. Test verification and validation for molecular diagnostic assays. *Arch Pathol Lab Med* **136**:11–13.

33. Gronowski AM, **Budelier MM**, **Campbell SM**. 2019. Ethics for laboratory medicine. *Clin Chem* **65**:1497–1507.

34. Barenfanger J, **Short MA**, **Groesch AA**. 2001. Improved antimicrobial interventions have benefits. *J Clin Microbiol* **39**:2823–2828.

35. Clinical and Laboratory Standards Institute. 2017. Developing and managing a medical laboratory (test) utilization management program. GP49. Clinical and Laboratory Standards Institute, Wayne, PA.

36. Dickerson JA, **Fletcher AH**, **Procop G**, **Keren DF**, **Singh IR**, **Garcia JJ**, **Carpenter RB**, **Miles J**, **Jackson B**, **Astion ML**. 2017. Transforming laboratory utilization review into laboratory stewardship: guidelines by the PLUGS national committee for laboratory stewardship. *J Appl Lab Med* **2**:259–268.

本书版权归John Wiley & Sons Inc.所有

37. Jacobs IA, Kelly K, Valenziano C, Chevinsky AH, Pawar J, Jones C. 2000. Cost savings associated with changes in routine laboratory tests ordered for victims of trauma. *Am Surg* **66**:579–584.

38. Toubert ME, Chevret S, Cassinat B, Schlageter MH, Beressi JP, Rain JD. 2000. From guidelines to hospital practice: reducing inappropriate ordering of thyroid hormone and antibody tests. *Eur J Endocrinol* **142**:605–610.

39. Valenstein P, Pfaller M, Yungbluth M. 1996. The use and abuse of routine stool microbiology: a College of American Pathologists Q-probes study of 601 institutions. *Arch Pathol Lab Med* **120**:206–211.

40. Silverstein JC, Rothschild AS. 1999. Clinical perspectives on the modern laboratory. *Clin Lab Med* **19**:421–432.

41. Cadogan SL, Browne JP, Bradley CP, Cahill MR. 2015. The effectiveness of interventions to improve laboratory requesting patterns among primary care physicians: a systematic review. *Implement Sci* **10**:167.

42. Farmer SA, Moghtaderi A, Schilsky S, Magid D, Sage W, Allen N, Masoudi FA, Dor A, Black B. 2018. Association of medical liability reform with clinician approach to coronary artery disease management. *JAMA Cardiol* **3**:609–618.

43. Miller WG, Tate JR, Barth JH, Jones GRD. 2014. Harmonization: the sample, the measurement, and the report. *Ann Lab Med* **34**:187–197.

44. Van Cott EM. 2014. Laboratory test interpretations and algorithms in utilization management. *Clin Chim Acta* **427**:188–192.

45. Gibson BA, McKinnon E, Bentley RC, Mohlman J, Witt BL, Yang EJ, Geisler D, DeFrances M. 2022. Communicating certainty in pathology reports. *Arch Pathol Lab Med* **146**:886–893.

46. Plebani M. 2009. Interpretative commenting: a tool for improving the laboratory-clinical interface. *Clin Chim Acta* **404**:46–51.

47. Kron K, Myers S, Volk L, Nathan A, Neri P, Salazar A, Amato MG, Wright A, Karmiy S, McCord S, Seoane-Vazquez E, Eguale T, Rodriguez-Monguio R, Bates DW, Schiff G. 2018. Incorporating medication indications into the prescribing process. *Am J Health Syst Pharm* **75**:774–783.

48. Mody L, Greene MT, Meddings J, Krein SL, McNamara SE, Trautner BW, Ratz D, Stone ND, Min L, Schweon SJ, Rolle AJ, Olmsted RN, Burwen DR, Battles J, Edson B, Saint S. 2017. A national implementation project to prevent catheter-associated urinary tract infection in nursing home residents. *JAMA Intern Med* **177**:1154–1162.

49. Schubart JR, Fowler CE, Donowitz GR, Connors AF Jr. 2001. Algorithm-based decision rules to safely reduce laboratory test ordering. *Stud Health Technol Inform* **84**:523–527.

50. Kilgore M, Hensley L, Howard C, Craft J, Smith JA. 1999. Curbing overutilization: the silver lining to HCFA compliance. *MLO Med Lab Obs* **31**:26–28.

51. Centers for Medicare & Medicaid Services. 2023. FFS ABN. https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN. Accessed 10 October 2022.

52. Kasprak J. 2008. Patient direct access to medical test results. OLR Research Report. Office of Legislative Research, Connecticut General Assembly, Hartford, CT. https://www.cga.ct.gov/2008/rpt/2008-R-0419.htm. Accessed 10 October 2022.

53. Dube N. 2013. Direct patient access to lab test results. OLR Research Report. Office of Legislative Research, Connecticut General Assembly, Hartford, CT. https://www.cga.ct.gov/2008/rpt/2008-R-0419.htm. Accessed 10 October 2022.

54. Heffner DK, Adair CF. 1999. Clarity on the diagnosis line (the devil is in the details). *Ann Diagn Pathol* **3**:187–191.

55. Thomas JG. 2000. Outcomes assessment: empowerment for microbiologists. *Adv Lab* **9**:54–60.

56. Lundberg GD. 1999. How clinicians should use the diagnostic laboratory in a changing medical world. *Clin Chim Acta* **280**:3–11.

57. Porter ME, Larsson S, Lee TH. 2016. Standardizing patient outcomes measurement. *N Engl J Med* **374**:504–506.

58. Barenfanger J. 2001. Clinical microbiology laboratories can directly benefit patients. *ASM News* **67**:71–77.

59. Gums JG, Yancey RW Jr, Hamilton CA, Kubilis PS. 1999. A randomized, prospective study measuring outcomes after antibiotic therapy intervention by a multidisciplinary consult team. *Pharmacotherapy* **19**:1369–1377.

60. Southwick K. 2002. Antibiotic alert: labs, pharmacies take on cost and misuse. *CAP Today* **16**:62–71.

61. Kollef MH, Ward S. 1998. The influence of mini-BAL cultures on patient outcomes: implications for the antibiotic management of ventilator-associated pneumonia. *Chest* **113**:412–420.

62. College of American Pathologists. Education: CAP patient outcome templates. https://www.cap.org/search?q=patient%20outcome%20templates. Accessed 11 October 2022.

本书版权归John Wiley & Sons Inc.所有

24

Introduction
Defining the Laboratory's Requirements
Technical/Performance Considerations
Specimen Type • Specimen Volume • Test Menu • Testing Volumes • Turnaround Time/Batch Size • Operational Throughput • Automation and Digitalization • Open versus Closed Platform • Available Interface • Assay Performance • Regulatory Clearance/Approval • Reagent Availability • Control Availability
Physical and Technology Requirements
Space Requirement • Power • Data • Plumbing/Water • Temperature/Humidity • Supply Chain Logistics
Human Resources
Staffing • Workflow • Ease of Use • Training Requirements
Financial
Instrument Cost • Cost of Operation • Cost per Result • Warranty • Maintenance Contract • Consumable Costs • Disposable and Consumable Cost • Software Requirements • Evaluation and Validation • Personnel Costs
Prioritization of Requirements
Confidentiality and Conflict of Interest
Information Review
Implementation and Product Placement
Verification and Validation
Verification • Validation
Personnel Competency Assessment and Training
Proficiency Testing
SUMMARY
KEY POINTS
REFERENCES

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch24.

Selection and Implementation of New Equipment and Procedures

Paula Revell and Lakshmi Chandramohan

OBJECTIVES

To establish the requirements that mandate acquisition and implementation of new equipment or procedures

To list the practical considerations involved in the selection and implementation of new equipment or procedure(s)

To describe the preevaluation and information gathering stages of planning, selection, and decision making

To review the process of implementation of new equipment or procedures

He that will not apply new remedies must expect new evils; for time is the greatest innovator.

Francis Bacon, *Essays*, II, On Innovation

TO OFFER THE BEST POSSIBLE CARE for the patients they serve, clinical laboratories are in constant need of newer and more efficient diagnostic testing methods. The ever-evolving understanding of diagnostic medicine and the constant quest for quality improvement are important drivers for the acquisition of new equipment and/or implementation of new procedures. In addition to the drive to improve quality of care, other factors such as limited financial resources and reduced availability of laboratory scientists are important considerations and are unique to each institution's testing environment. Furthermore, as seen during the COVID-19 pandemic, clinical laboratories worldwide can be plagued by supply chain disruptions while struggling to meet increased laboratory testing demand. A critical mistake during the selection process not only impacts the organization's financial resources but also affects the workflow, staffing, and turnaround times and can result in less-than-optimal patient care.

The selection of new laboratory equipment or procedures is complex and time-consuming. Faced with changing clinical needs and limited financial resources, laboratorians must make difficult choices about which new equipment, technology, procedures, and assays, or combinations of these, to acquire and implement and how to incorporate them into their diagnostic laboratories. The choice of which equipment to buy or replace may be further confused by conflicting advice and persuasive salesmanship, as well as the rapidly changing regulatory environment. The selection process calls for a clear understanding of

本书版权归John Wiley & Sons Inc.所有

the principal need for the acquisition of the new equipment, and the selection process must be carried out in an objective manner, considering the practicality, reliability, and fitness for purpose with input from potential end users, clinicians, and management teams.

Some common scenarios that lead laboratorians to initiate the selection process include replacement of old equipment because it is no longer able to meet the laboratory's clinical needs, has become excessively expensive to maintain, and/or is no longer supported by the manufacturer, and the need to acquire new technology that provides the laboratory with opportunities to improve the quality of patient care by expanding or updating the test menu (1). Every laboratory has its unique requirements. Since there is no "one size fits all" approach, there are no official guidelines or regulations to guide laboratorians in this decision-making process. This chapter will serve as an overview of the important considerations involved in the selection and acquisition of new equipment and the implementation of new procedures in a diagnostic laboratory.

For any purchase or implementation, it is imperative to look at the big picture. Caveats to be considered include: (i) does the introduced change provide information of significant clinical utility to the clinicians and patients? (ii) does it facilitate the recapture of resources and generate long-term and short-term cost benefits? (iii) will this acquisition interact with other technology or personnel within the laboratory? and (iv) how will future upgrades, expansions, or consolidations be impacted by it? Other factors that will play a vital part in the selection process are current and projected test volumes, instrument flexibility and throughput, laboratory information system (LIS) and infrastructure requirements, impact on staffing, and maintenance (2).

The introduction of new equipment or procedures into the routine clinical laboratory is a three-stage process that involves (i) planning and selection, (ii) method verification and validation, and (iii) implementation and continuous monitoring of the performance (3). Much of this chapter will focus on the selection and decision-making process involved in introducing new equipment and/or procedures and will briefly review the other two processes.

Defining the Laboratory's Requirements

Prior to the acquisition or implementation of any new diagnostic equipment or assay, it is critical that the laboratory defines exactly what is driving the potential process change. New processes or procedures can offer tremendous benefits ranging from improved workflow to increased volume and throughput to increased efficiencies that lead to cost savings; however, the laboratory may fail to achieve these benefits if the specific problems are not well defined. With the increasing arsenal of diagnostic options today, it becomes imperative to ask the right questions during the planning and selection process. The definition of the laboratory's requirements depends on what the clinical needs are now as well as what is planned. Some examples of factors that may drive process change include but are not limited to the following:

- Changing clinical needs of the community served by the laboratory; for instance, emergence of new diseases (COVID-19); responding to acute, disproportionate demand for testing due to regional outbreaks; or new patient populations with unique testing needs. For example, the opening of a maternity center that adds a new patient population focused on labor and delivery will require that the laboratories serving this center implement a process change to accommodate the center's clinical needs.
- New guidelines or recommendations for diagnostic testing by agencies such as the Centers for Disease Control and Prevention (CDC) (http://www.cdc.gov/labstandards/, accessed 5 July 2022) and the World Health Organization (WHO; http://www.who.int/en/, accessed 5 July 2022), e.g., the CDC's testing guidelines for SARS-CoV-2.
- Emergence of new and promising technologies (instrumentation or procedures) with better testing accuracy, improved clinical performance, reduced cost per test, and multianalyte testing, e.g., converting culture-based testing to rapid, automated, multiplex nucleic acid-based *in vitro* diagnostic testing, or direct pathogen detection from blood.
- A need for improved turnaround times for critical tests, which in turn produces quicker diagnosis and timely initiation of therapy, e.g., testing for neonatal central nervous system infections caused by herpes simplex virus.
- Clinicians' interest in providing tests that have improved diagnostic confidence as a result of improved feasibility and interpretability, e.g., introducing tests that the clinician can easily interpret with reduced frequency of indeterminate results.
- Preparing for possible supply chain challenges by evaluating alternative testing options; for instance, during the COVID-19 pandemic, laboratories faced laboratory supply shortages that included but were not limited to blood collection tubes, reagents, needles, pipette tips, syringes, culture and transport media, and personal protective equipment (PPE), thereby impacting day-to-day laboratory operations.

Once you establish the drivers or needs that mandate acquisition and implementation of a new instrument or procedure, you must gather both objective and subjective information to facilitate the decision-making process. The following section will attempt to provide a comprehensive

本书版权归John Wiley & Sons Inc.所有

list of practical considerations that may be important factors in choosing the best instrument or assay for a specific laboratory or a group of associated laboratories.

Every laboratory is unique, with various aspects driving the acquisition of new platforms or the implementation of new assays or procedures. Discussed below and listed in Table 24.1 are potential factors to consider; however, due to the varying needs of each individual laboratory, this list is not intended to be a universal fit for all data collection prior to choosing or implementing a platform, but rather is a starting point from which managers and directors can begin gathering relevant information to aid in making the most informed and educated decision possible. The following sections describe in detail several of the objective and subjective considerations for which information should be collected to aid in the decision-making process.

Table 24.1 Factors to consider prior to the acquisition of new equipment or implementation of new procedures

Technical/performance considerations
Specimen types
Specimen volumes
Test menu
Current menu
Expansion capability and history of vendor offering new assays as planned
Testing volumes
Turnaround time/batch size
Time from sample loading to result reporting
STAT result capability for some/all tests offered
Batch processing capability for specimen testing and/or reporting
Random access
Operational throughput
Maximum capability of testing offered per shift or per day
Onboard time
Automation and digitalization
Open versus closed platform
LIS interfacing capability (bidirectional, ease of maintenance)
Assay performance
Sensitivity and specificity
Assay precision, accuracy, and linearity
Regulatory clearance/approval
FDA cleared/approved assays
Complexity of offered testing
Reagent availability
Identify key reagents and their availability
Qualification/validation of alternative options
Control availability
Available from the manufacturer
Control usage and type if supplied
QC tracking programs
Proficiency testing
Physical and technology requirements
Labor space requirement
Power
Can current power supply support the platform?
Requirements for additional or backup power
Data
Onboard data management
Linking with lab automation systems
Plumbing/water system
External plumbing
Waste disposal system
Temperature/humidity requirements
Requirements for additional ventilation and air conditioning
Supply chain
Lead times, availability of parts
Impact of raw material shortages and logistics delays
Human resources requirements
Staffing
Workflow
Running the assay all shifts
Hands-on time
Ease of use
Complexity of operation
Ease of troubleshooting
Error alerts (audio/visual)
Training requirements
Off-site/on-site training
Number of staff that can be initially trained
Future training of staff available with/without charge by vendor
Financial considerations
Instrument cost
Cost of operation
Cost per result
Warranty
Maintenance contract
Other costs (consumable and disposable costs, software requirements, reimbursement)

Technical/Performance Considerations

Specimen Type

Specimen types received in the laboratory include, for example, whole blood, CSF, serum, plasma, etc. This factor is critical to performance considerations in terms of the flexibility of various platforms or assays; a platform with limited specimen flexibility will have limited flexibility in routine laboratory operations. Additionally, it is critical to consider what specimen types are currently being used for a given assay if the laboratory is transitioning to a new platform or assay rather than bringing in something new. Education and training regarding new specimen type requirements as well as proper specimen collection will be an essential aspect of implementation if there are new specimen requirements.

Specimen Volume

What are the minimum and maximum specimen volumes required to run the assay? This volume should include the dead volume and can be an issue particularly for pediatric specimens and short collections. The sample volume requirement can also be an issue for shared specimens or

本书版权归John Wiley & Sons Inc.所有

limited-volume specimens such as CSF and pleural fluid. Additionally, specimen processing methods (manual versus automated) as well as their individual specimen volume specifications must be considered prior to implementation.

Test Menu

What assays/tests are offered on a platform? Does the platform offer multiple test options and thus increase the flexibility and growth potential? This is an important consideration given the decreasing budgets of many modern laboratories; by offering multiple assays on one platform, the laboratory can often increase efficiency and decrease reagent cost due to volume-based purchasing of reagents.

Testing Volumes

What is the estimated testing volume? How often will the new platform/assay be used? Can the platform support the expected testing volumes?

Turnaround Time/Batch Size

What is the total elapsed time from sample loading to reporting results? Are STAT results needed for some or all the tests offered on the platform? Are specimens tested in a batch capacity, and if so, what are the batch sizes? Does the platform offer truly random-access testing or partially random-access testing? Some platforms claim a "random-access" feature, but there may be limitations such as the inability to interrupt a batch run to perform a different test type or run a different sample type. Are the results continuously reported, or are results reported in a "batch" format?

Operational Throughput

What is the maximum capacity of testing offered per shift or per day? The throughput incorporates multiple variables, including the number of samples that can be loaded onto the platform at one time and the total "onboard time" for any given sample. For example, a completely random-access platform with a single reaction chamber and an onboard time of 2 hours would have a throughput of 12 tests per 24 hours. Other variables that can influence throughput include the "hands-on time" for sample preparation and the time required to load the samples onto the platform. The throughput may change for various combinations of specimen types or assays, and all potential profiles should be considered. It is important to consider not only whether the throughput will meet existing needs, particularly at peak demand, but also whether it will allow for potential future growth.

Automation and Digitalization

How easily can the platform/assay be integrated with existing labware? Can the platform/assay be adapted into a targeted workflow or total laboratory automated workflows with minimal disruptions? Does the manufacturer offer to support the organization's short- and long-term goals for integrated workflows? For example, it is critical to evaluate the flexibility of the platform to support automation of workflows (such as use of liquid-handling robotic arms for specimen dispensation or processing) as the laboratory's clinical needs expand (4).

Open versus Closed Platform

Does your laboratory have any plans for internal assay development? Some platforms allow for laboratory test development, while others only allow vendor-specific assays and reagents.

Available Interface

Does the system interface effectively with any LIS, and if so, is the system compatible with your laboratory's LIS? The ability to directly transmit results from the testing platform to the LIS and to avoid manual data entry is a critical factor in terms of improving patient safety through accurate result reporting. Additionally, selecting a middleware solution with a comprehensive set of functionalities that are best suited to address the laboratory's complex data management, sample and test management, and workload challenges would be critical.

Assay Performance

Determining assay performance requires objective measures of an instrument or assay, such as precision, accuracy, linearity, sensitivity, and specificity. It is important to know how the numbers reported by the vendor were determined. During the evaluation period the laboratory must verify the performance of these objective measures through the validation process. Laboratories need to be aware of both the analytical performance (usually reported by the manufacturer) as well as the clinical performance, which is much more difficult to determine. The specific needs of your patient population should be considered.

Regulatory Clearance/Approval

The U.S. Food and Drug Administration (FDA) regulates all medical devices, and platforms and assays fall under this umbrella. It is critical to understand the specific classification of the instrument or assay you are considering for your laboratory. Most platforms must be FDA cleared to be marketed in the United States; however, there is much more variability regarding commercially available assays. Assays can be considered for research use only (RUO), analyte-specific reagents (ASR), Emergency Use Authorization (EUA), FDA cleared, or FDA approved. EUAs are granted by FDA to expedite the availability of medical products, including drugs, vaccines, and medical devices, during public health emergencies. For example,

本书版权归John Wiley & Sons Inc.所有

EUAs have been extensively used during the current COVID-19 pandemic, and any COVID-19 diagnostic or serology test that is available for public use had to be granted EUA status before it could be used. It is important to note that EUAs can be revised or revoked at any time and are only effective until the emergency declaration ends. FDA clearance indicates the establishment of analytical performance for the assay by the manufacturer when the assay is performed exactly as described in the package insert. FDA approval indicates that not only have analytical performance characteristics been established, but also clinical performance characteristics. FDA-approved assays are much less commonly available; examples include next-generation sequencing assays for human pathogen detection and identification in clinical specimens, HIV and hepatitis C RNA viral load assays, as well as others. FDA-cleared assays are also given an additional designation regarding the complexity of testing. "Waived" tests are considered the simplest and can be run as point-of-care assays; additional designations include moderate-complexity and high-complexity tests. The designated level of complexity significantly determines who in the laboratory can perform the various assays.

Reagent Availability

It is critical to assess what types of reagents and consumables are required, and whether these are custom-order or readily available. Are these reagents only available from one vendor or can they be widely sourced? Laboratories may be used to purchasing specific brands or working with certain vendors; however, alternative options may have to be considered to meet deadlines and budgets. Additionally, proactive planning to verify or validate these alternative options should be included as a part of new platform/assay implementation.

Control Availability

Many vendors sell controls, and thus availability is generally not an issue; however, this is an important factor to consider because for certain assays controls are not available commercially, and thus issues such as consistency and reliability can become limitations to assay performance.

Physical and Technology Requirements

Space Requirement

What are the physical specifications of the equipment, including size and weight, and how will the instrument fit in the laboratory and within any existing workstations if applicable? Additionally, it is important to consider not just the physical footprint of the instrument but also the space needed for proper ventilation and access required for routine maintenance and servicing of the instrument. In certain parts of the country, natural disaster issues must also be considered (earthquake protection and equipment lock-down; potential flooding for floor models).

Power

Will the existing power supply in the laboratory be sufficient to support the operation of the equipment? Will additional dedicated or backup power be required? Alterations to existing electrical supply can significantly increase the overall cost of implementation.

Data

If the instrument will require a connection to the internet for cloud-based services or be interfaced with other equipment or the LIS, the data line requirements must be carefully evaluated.

Plumbing/Water

Some instruments require high-quality water supplies or direct access to plumbing to remove waste.

Temperature/Humidity

Most equipment requires specific environmental controls to operate optimally. Consider not just the existing environmental conditions but also the impact the addition of the new equipment will have through heat production, etc. Ventilation and air conditioning are critical factors for optimal instrument performance.

Supply Chain Logistics

Is the platform/assay custom-built or part of a standard inventory that is maintained by the manufacturer? Is the equipment and/or parts manufactured in the country where the laboratory resides, or do they have to be imported? How might raw material shortages or logistics delays impact lead times? These questions will help to ensure that laboratories make the most informed business decision relating to the procurement of laboratory equipment and supplies.

Human Resources

Staffing

What is the number of staff required to operate the equipment, and what level of skill and expertise is required of the staff? How will the implementation of the platform impact current staffing levels? Depending on the assay or instrument in question, staffing requirements could go up or down. With automation or platforms that require less hands-on time, the new instrumentation could free up existing staff to perform different laboratory tasks.

Workflow

Can the equipment or assay be run during all shifts? What is the required hands-on time? How will the addition of

本书版权归John Wiley & Sons Inc.所有

the new assay or platform impact existing work practices? All aspects of testing need to be included in the evaluation, not only direct testing but sample preparation time, quality control practices, and maintenance.

Ease of Use

Do the technologists who will use the instrument find it "user friendly"?

Training Requirements

What types of training are required prior to implementation, and are training programs offered by the vendor? Is there an additional cost associated with the required training?

Financial

Instrument Cost

In addition to the actual cost of the equipment, what are the available options for purchasing or financing? Additionally, it would be important to explore whether there are options for lease or reagent rental agreements. For laboratories with limited capital funds for upfront instrument purchase, leasing or reagent rental are viable options. While instrument leasing allows the flexibility and tax benefits, reagent rental can offer the advantage of lower cost per test. However, to fully evaluate the benefits of leasing or reagent rental over instrument purchase, a careful review of lease terms and agreement, type of lease, and an accurate estimate of test volumes over the length of the agreement would be necessary. As reagent rentals are based on reagent commitments and testing volumes, laboratories will incur penalties for decreased usage, will lose the lower cost per test advantage, or will eventually end up with the equipment being paid for more than once without gaining ownership.

Cost of Operation

What are the direct and indirect costs over the lifetime of the instrument?

Cost per Result

The estimated cost per result involves a variety of factors including the cost of reagents, disposables, calibrators, controls, labor, maintenance, repeats, etc. Additionally, it is important to have a good idea of the volume of samples you will be running, as the cost of reagents is typically impacted by the volume of reagent purchased from the vendor.

Warranty

Most instruments come with a warranty; however, these warranties vary widely in terms of the warranty period, service contract terms and conditions, and the return or cancellation policy. Understanding when the warranty begins and expires, what causes the warranty to become void, loaner instrument and shipping costs during repair, availability and need for extended warranty, and the warranty claim process are critical factors when considering new equipment.

Maintenance Contract

The details of the annual maintenance contract should be discussed up front, as they can vary widely and significantly impact the cost to operate the equipment. Details should include what is covered by the annual contract as well as the cost of additional requirements such as after-hours or holiday repair calls and parts that need to be replaced on maintenance schedules (e.g., bulbs, probes, etc.).

Consumable Costs

What are the estimated reagent, calibrator, and control costs given the laboratory's estimated test volume? Important factors to consider in this analysis include the size of the reagent kits and their shelf life once opened. If a vendor sells only large kits and the shelf life of reagents is short, a laboratory may end up paying for wasted reagents, increasing the cost unnecessarily.

Disposable and Consumable Cost

What are the costs for tips, reagent bins, etc.?

Software Requirements

Are there up-front costs associated with software purchases, and will there be costs associated with software upgrades? Is there a cost associated with the implementation of an LIS interface? Who will be handling the upgrades, interface, etc. (company or laboratory personnel)?

Evaluation and Validation

What are the costs associated with equipment evaluation prior to the purchase, and if purchased, what will be the cost to properly verify and validate performance characteristics? Keep in mind that if the laboratory is transitioning to a new or different technology, platform, or assay, physician end users may need to see extensive parallel testing to know how to appropriately apply new diagnostic values.

Personnel Costs

What are the costs associated with travel, hotel, meals, etc., for laboratory personnel undergoing training off-site?

Prioritization of Requirements

Once the decision has been made as to what the laboratory needs and wants from a given assay or platform, and the data regarding the subjective and objective specifications of available platforms or assays have been collected, the list

本书版权归John Wiley & Sons Inc.所有

of possible choices will be narrowed due to elimination of those products that do not meet the minimal criteria. Prioritizing the desired features that are not minimum requirements can further refine the list of possible choices that meet the laboratory's basic needs.

In today's environment of limited budgets and higher demands on productivity, whether the final decision about which assay or instrument to implement is left to the individual supervisor or director, or more commonly to a team of decision makers including administrators, clinicians, and even hospital board members, communication regarding the final choice is critical. A clear and concise presentation of the logic and motivation behind the decision to purchase any given platform can be the difference between a successful purchase and a failed attempt. Whether an individual or team-based decision-making process is employed, this is dependent on the type of purchase, product quality, intrinsic value, and business impact. For small benchtop equipment such as centrifuges and microplate readers, this decision may be made by an individual such as a section supervisor or a bench technician, in contrast to large equipment purchases or new assay implementation. In such situations, an integrative strategic process involving individual and team-based decision-making approaches would be critical. The initial research and requirements gathering may be performed by subject matter experts and/or end users in the specific area, followed by subsequent presentation of data and justification to a team of decision makers, ensuring participation from all stakeholders. In situations where a team of decision makers is involved, be cognizant of the fact that many of the team members may not be experts in the area for which the equipment will be purchased.

Confidentiality and Conflict of Interest

Throughout the entire process of selection and decision making, it is critical that all those involved in the process remain independent, free of obligation or suspicion, and completely fair and impartial. Maintaining the integrity, credibility, and confidentiality of selection and acquisition of equipment requires a clear set of guidelines, rules, and responsibilities to govern the behavior of the decision makers. For example, an employee or team member may not solicit or accept anything of value from an actual or potential manufacturer or vendor, be employed by or agree to work for a vendor or potential vendor, or knowingly disclose confidential information for personal gain. Those involved in the selection process are not permitted to communicate about or discuss the procurement or evaluation process with any other employee who is not involved in this process. Furthermore, the employees and team members shall not disclose the scoring outcomes or content of the proposals. Depending on the institution, all those who have been delegated the authority to purchase may also be required to sign a conflict-of-interest statement each year. In case of an actual or potential violation, the employee or team member involved may be reprimanded, suspended, or dismissed. The manufacturer or vendor may be barred from receiving future contracts and/or have an existing contract canceled.

Information Review

Once the laboratory's requirements for introducing new equipment and/or a new procedure have been clearly defined, the next critical step in the selection process is preevaluation and information review. It is important to review the latest information on as many commercially available platforms and procedures as possible can via thorough internet searches (PubMed, manufacturer's websites, and commercial advertisements), review of trade journals and existing literature, review of manufacturers' package inserts, and conversations with vendors' representatives and other users. Accurate data collection is vital in choosing the appropriate system. Qualitative and/or quantitative data collection approaches may be used. The quantitative data collection involves having structured questions in the questionnaire, while qualitative data collection relies on open-ended questions in the questionnaires. It is critical to discuss potential new equipment or assays with all stakeholders who will be affected by the changes. For example, section supervisors, bench technicians, or those closely involved in the day-to-day laboratory operations would be able to provide valuable information and feedback regarding how the new equipment or assay would fit into the current workflow, if there are going to be any integration issues with the existing infrastructure, and any need for additional resources. Additionally, engaging with management, including those involved in supply chain management, can ensure informed decision making. Recommendations of relevant professional bodies such as the CDC, the Infectious Disease Society of America (http://www.idsociety.org/, accessed 5 July 2022), and the American Association for Clinical Chemistry (http://www.aacc.org, accessed 5 July 2022) and regulatory agencies such as the College of American Pathologists (CAP; http://www.cap.org, accessed 5 July 2022) and the Clinical and Laboratory Standards Institute (CLSI; http://www.clsi.org/, accessed 5 July 2022), as well as clinical outcome trials, presentation at professional conferences, and review of external quality assurance schemes (5) can be vital sources of information. Professional publications and specialty journals also have articles on clinical evaluations of equipment and procedures. Contact other laboratories or scientists who already have implemented a new system that might be of interest and ask them about cost, performance,

本书版权归John Wiley & Sons Inc.所有

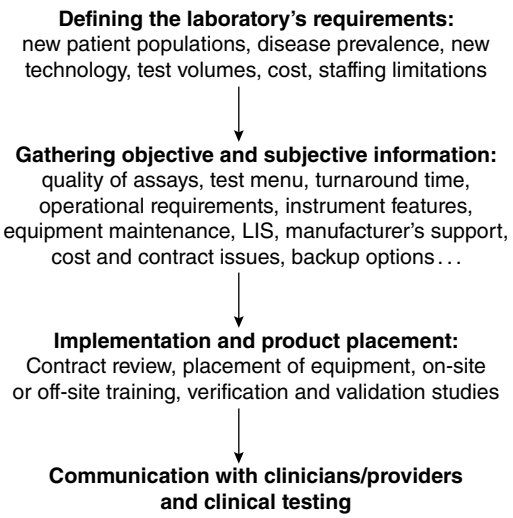


Figure 24.1 Overview of the selection of equipment and implementation of procedures.

reliability, and service. Assessment of available information is best performed by tabulating the data to compare variables that are high on the list of laboratory needs or wants. Select or short-list those that will best serve the laboratory's needs. Once the necessary information is tabulated, decision makers should meet to discuss the short-listed choices and the reasoning behind each selection criterion. The process can then be refined or modified as needed, with the modified criteria retabulated to address all issues of concern. Figure 24.1 provides an overview of the planning and selection of equipment or procedures leading to clinical implementation in the laboratory for routine patient care.

Implementation and Product Placement

The implementation of a new procedure or instrument requires coordination between the placement site and the vendor. Typically, the vendor requires the placement site to fill out questionnaires regarding the physical characteristics of the space, and then the vendor will inspect the site to clarify what, if any, physical changes might be required prior to placement. The timing of the purchase can be significantly affected by any required changes to the space such as electric, plumbing, data, etc. If the purchase of an instrument is delayed, this can impact the original quoted price, so laboratories need to be diligent about planning and coordinating the entire process.

Once the instrument is placed, many vendors offer on-site training of key laboratory personnel. After key personnel have been trained on the operation of the instrument or performance of the assay, the laboratory is responsible for verification and validation of the new purchase.

Verification and Validation

On acquisition of equipment and/or implementation of new procedures, laboratories are required to establish policies and procedures to maintain or improve the reliability, efficiency, and clinical utility of the testing systems. Two critical analyses performed in the laboratory are method verification and validation. These processes provide critical objective evidence that the chosen system is fit for purpose, meaning that the requirements for a specific intended use are fulfilled.

Verification

According to Cumulative Techniques and Procedures in Clinical Microbiology (*Cumitech*) (6), verification is the one-time process performed to determine or to confirm a test's expected performance prior to implementation in the clinical laboratory. Verification requires determination of performance characteristics that include sensitivity, specificity, predictive values, precision, and accuracy of the test. In contrast, validation is an ongoing process of monitoring a test, procedure, or method to ensure that it continuously performs as expected. Laboratories can use some aspects of verification testing for other purposes; for example, precision testing for a verification can simultaneously be used as a training/competency panel for personnel or to qualify multiple extraction and real-time instruments for the test. Laboratories may consider modified verification strategies during supply and reagent shortages; for example, mini verification panels may be developed and used to verify assay or platform performance (7).

Validation

According to CLIA (http://wwwn.cdc.gov/clia/, accessed 5 July 2022), validation is an integral part of a laboratory's quality assurance programs, and it requires personnel competency assessment, quality control, internal and external proficiency testing, and correlation with clinical findings. It is important to note that the definitions for verification and validation as written above are accepted by CLSI, CLIA, and the International Organization for Standardization (ISO). However, the definitions accepted by CAP are the inverse. CLIA requires that for FDA-cleared and -approved tests, a laboratory must document its verification of the following four performance characteristics: accuracy, precision, reference range, and reportable range. These performance characteristics are published in the manufacturer's package insert. Furthermore, laboratories performing laboratory-developed tests (LDTs) and modified FDA-cleared and -approved tests are required to "establish" the same four performance characteristics that are required for FDA-cleared and -approved tests, as well as to determine the analytic sensitivity, analytic specificity, and any additional performance characteristics. Verification or validation of molecular panels for pathogen

本书版权归John Wiley & Sons Inc.所有

detection often requires a diverse selection of relevant clinical specimen types (e.g., cerebrospinal fluid, wound specimens, etc.) as well as pathogens collected from the affected patient populations, along with appropriate positive and negative control specimens. Prior to onset of validating an assay, it would be important to identify various specimen sources as well as commercial or third-party vendors that are able to supply relevant specimens and controls in various matrices that are being validated. The relevant controls and clinical specimens may also be compounded by limited supply of specimen collection devices, transport media, or test reagents, thus delaying the time to launch of a new assay or panel. It is also important to keep in mind that the processes of verification and validation as well as specimen procurement add to the cost of implementation of a new laboratory testing system.

Personnel Competency Assessment and Training

Establishing the competency of each laboratory employee is an extremely important component of laboratory quality control. It ensures that personnel are trained appropriately to perform prompt and accurate clinical testing. All newly implemented tests or testing procedures must have proper, documented personnel training before patient results can be reported. The competency of all personnel must be assessed semiannually during the first year of their employment and then annually thereafter (8, 9). According to CLIA, the necessary components of a competency assessment program are (i) direct observation of performance during routine testing; (ii) monitoring of recording and reporting of patient results; (iii) review of worksheets, quality control records, proficiency testing results, and preventive maintenance records; (iv) direct observation of performance of instrument maintenance and function; (v) assessment of test performance through testing of previously analyzed specimens, internal blind testing, or external proficiency testing samples; and (vi) problem-solving skills assessment. Training is required before a new or current employee can perform a new test or when a new assay is introduced. Training updates are required whenever changes are implemented to a procedure or when new learning objectives are added to the training document.

Proficiency Testing

Proficiency testing (PT) is a critical tool used by clinical laboratories to verify the accuracy and reliability of their testing (10). Laboratories that are CLIA certified are required to enroll in a Centers for Medicare and Medicaid Services-approved (11) proficiency program for each specialty and subspecialty for which certification is sought. Routine reviews of PT reports by the laboratory director and staff will help determine areas of testing that are not performing as expected and also will indicate subtle shifts and trends that, over time, would affect patient results. Proficiency samples are tested in the same manner as any other patient sample. A score of at least 80% is required for satisfactory performance. The laboratory must establish an internal proficiency program for those tests that have no external PT programs available (10). When developing an internal proficiency program, a thorough and careful review of test performance, workflow, and quality control checks is important. As a part of this program, it would be the laboratory director or designee's responsibility to determine the appropriate mix of PT samples based on the complexity of the test/procedure. Importantly, there must be policies in place to quickly identify failures, investigate processes, assess impact on patient results, and implement remedial actions in a timely manner. Monitoring and disseminating information about trends in PT performance during the ongoing implementation of the CLIA regulations can assist individual laboratories in assessing their performance relative to other laboratories.

SUMMARY

The overall value of diagnostic testing is measured not only by its analytical performance or financial value but also by how well it meets the clinical needs of the clinicians and patients. Thus, establishing benefit to patient health is the primary driving force when introducing changes in routine diagnostic testing. The critical nature of communication with the clinicians or community health workers who will be using the laboratory tests cannot be overemphasized. It is important to remember that a new diagnostic system must be examined as a part of a broader management strategy.

Although this chapter has emphasized the objective consequences of a process change due to either acquisition of equipment or implementation of procedures, other variables such as clinicians' views and diagnostic confidence can positively or negatively influence the outcome of any process change. Clinicians' perspectives of testing, their experience with the testing process, and their understanding of the test can all affect downstream patient care. The clinicians who utilize the new procedure must agree that its performance characteristics are satisfactory and meet the clinical need. To purchase equipment simply because it is economically feasible may not be in the best interest of the laboratory. Therefore, whenever possible, the selection process should be performed while keeping in mind the range of conditions in which the intended equipment or procedure is likely to be used in routine clinical practice.

本书版权归John Wiley & Sons Inc.所有

KEY POINTS

- Defining the requirements that mandate the laboratory's purchase and implementation of new equipment and/or procedures is the first and most critical component of the planning and selection process.
- Practical considerations when choosing the best instrument or assay for a specific lab include testing volumes, specimen types, test menu, turnaround time, operational throughput, physical requirements, assay performance, cost, manufacturer's contract and warranty, computer interfacing, and staffing considerations.
- Method verification, validations, competency, proficiency testing, and training are required before new equipment or procedures can be implemented in a clinical laboratory.
- Throughout the process, timely and accurate communication with end users is critical to the successful purchase and implementation of any new laboratory equipment or procedure.

REFERENCES

1. **Myers J.** 2007. Primer for selecting lab equipment. *MLO Med Lab Obs* **39**:26–27.

2. **Mina A**, **Favaloro EJ**, **Koutts J**. 2008. A practical approach to instrument selection, evaluation, basic financial management and implementation in pathology and research. *Clin Chem Lab Med* **46**:1223–1229.

3. **Murphy PG**. 2008. Selection of a suitable assay. *Clin Biochem Rev* **29**(Suppl 1):S17–S22.

4. **Leo S**, **Cherkaoui A**, **Renzi G**, **Schrenzel J**. 2020. Mini Review: Clinical routine microbiology in the era of automation and digital health. *Front Cell Infect Microbiol* **10**:582028.

5. **Olson JD**, **Preston FE**, **Nichols WL**. 2007. External quality assurance in thrombosis and hemostasis: an international perspective. *Semin Thromb Hemost* **33**:220–225.

6. **Clark RB**. 2009. Cumitech 31A: Verification and validation of procedures in the clinical microbiology laboratory. Coordinating ed, Sharp SE. ASM Press, Washington, DC.

7. **Mitchell SL**, **St George K**, **Rhoads DD**, **Butler-Wu SM**, **Dharmarha V**, **McNult P**, **Miller MB**. 2020. Understanding, verifying, and implementing emergency use authorization molecular diagnostics for the detection of SARS-CoV-2 RNA. *J Clin Microbiol* **58**:e00796–20.

8. **CLSI**. 2016. Training and competence assessment. 4th ed. CLSI guideline QMS03. Clinical and Laboratory Standards Institute, Wayne, PA.

9. **Elder BL**. 2003. Cumitech 39: Competency assessment in the clinical microbiology laboratory. Coordinating ed, Sharp SE. ASM Press, Washington, DC.

10. **CLSI**. 2016. Using proficiency testing and alternative assessment to improve medical laboratory quality. 3rd ed. CLSI guideline QMS24. Clinical and Laboratory Standards Institute, Wayne, PA.

11. **CMS**. 2003. Medicare, Medicaid and CLIA programs: laboratory requirements relating to quality systems and certain personnel qualifications, final rules. *Fed Regist* **68**:3640–3714.

本书版权归John Wiley & Sons Inc.所有

25

Introduction
Safety Management Plan and Responsibilities
Laboratory Hazards
Biological Hazards • Chemical Hazards • Physical Hazards • Radiation Hazards • Mental Hazards
Standard Precautions
Hazard Prevention and Containment
Risk Assessment • Handwashing • Barrier Protection • Engineering Controls • Work Practices • Respiratory Protection • Immunization • Warning Signs and Labels • Biological Safety Cabinets and Chemical Fume Hoods
Sterilization and Decontamination
Spill Management
Biological • Chemical
Fire Safety
Disaster Preparedness
Waste Management
Regulatory Oversight • Management Program
Packaging and Shipping Infectious Substances
Infectious Substances Classification • Packaging, Labeling, and Shipping Regulated Material
Personnel Training
Training Program • Methods • Documentation • Monitoring and Evaluation
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES
APPENDIXES

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch25.

Laboratory Safety

Cameron A. Brown and James J. Dunn

OBJECTIVES

To define the essential components of a laboratory safety program
To administer the program to meet safety requirements
To evaluate the program for regulatory compliance
To identify hazardous materials and procedures in the laboratory

Before anything else, preparation is the key to success.

Alexander Graham Bell

THE LABORATORY ENVIRONMENT CAN BE A HAZARDOUS PLACE TO WORK. Laboratory workers are exposed to numerous potential hazards including chemical, biological, physical, and radioactive hazards, as well as musculoskeletal stresses. Laboratories, by the nature of the work performed, contain inherent risk to workers that is often difficult to measure and manage because safety is not an intrinsic, absolute, and measurable property (1). Therefore, we must continually assess and manage risk in the laboratory based on current knowledge and propose and enforce commonsense safety practices to minimize harm or injury to the worker and to prevent laboratory contamination (2). Accidents in the laboratory are often attributable to a person's inability to recognize a hazardous situation, an individual's diminished concern for risk over long periods of time, or excessive risk taking. Thus, an individual's behavior influences the degree of occupational risk present in the workplace (3). Risk takers and individuals who ignore safety precautions not only suffer the consequences from their acts but also pose a risk to their colleagues, families, and friends.

Biological hazards (e.g., exposure to blood, body fluids, and other potentially infectious materials [OPIM]) are a major concern for laboratory workers today and have heightened the need for implementation of sound safety practices. Exposure to these pathogens through specimens, aerosols, or droplets may cause an occupationally acquired infection that can be transmitted to other employees, employees' families, or the public. Today, the potential use of biological, chemical, and radioactive materials as terrorism agents imposes additional safety and security concerns in the laboratory (4–7).

Exposure to hazardous chemicals may result in acute and/or chronic disease that may be exacerbated in employees with preexisting medical conditions. Although there is a continuing effort to reduce the number and quantity of

本书版权归John Wiley & Sons Inc.所有

laboratory chemicals that are toxic, carcinogenic, caustic, flammable, or radioactive, many compounds have yet to be eliminated completely from laboratories.

In addition to biological, radiological, and chemical hazards, fires and electrical accidents may occur, and laboratory instruments and equipment may cause injury to the user. However, the laboratory can be a safe workplace when the risks are recognized and reduced through appropriate training of personnel and implementation of safe work practices, appropriate containment equipment, well-designed facilities, and administrative controls (8–13).

Many laboratories use a combination of control methods to protect workers. This hierarchy of controls prioritizes intervention strategies based on the premise that the best way to control a hazard is to systematically remove it from the workplace, rather than relying on workers to reduce their exposure. These types of measures, prioritized from the most effective to least effective, include engineering controls, administrative controls, work practices, and personal protective equipment (PPE).

Safety Management Plan and Responsibilities

The key to a safe laboratory environment is the development, implementation, and enforcement of a high-quality safety management program that considers worker safety as a responsibility of the facility (Table 25.1). The Occupational Safety and Health Administration (OSHA) requires a risk assessment (exposure determination) of each task performed in the laboratory. The safety program begins with a well-written safety manual that defines the program and identifies the individuals responsible for specific tasks (9, 14, 15). Management must commit to the program and provide the necessary resources (e.g., equipment and time) to produce and implement the plan, assign oversight and responsibility for the plan, and communicate the plan and expectations to the employees. The risk associated with each task performed in the laboratory is assessed, and practices are implemented to minimize these risks. These practices include the use of standard precautions, PPE, engineering and work practice controls, workplace design, vaccination, safe handling and disposal of hazardous waste, and use of safety devices (10). In addition, the safety plan should include sections on blood-borne pathogens, a medical surveillance program, a chemical hygiene plan, infection control procedures, hazard communications, record keeping, waste disposal, fire safety, and spill cleanup. The federal regulations that directly address general laboratory safety include Hazard Communication Standard 29 CFR 1910.1200 (16), Bloodborne Pathogens Standard 29 CFR 1910.1030 (17), and Occupational Exposure to Hazardous Chemicals in the Laboratory 29 CFR 1910.1450 (18).

Table 25.1 Elements of a safety management plan

Administrative support
Develop and maintain written safety information identifying workplace hazards.
Appoint a safety officer and members of the safety committee.
Appoint a chemical hygiene officer.
Appoint a radiation safety officer (if radioactive materials are used in testing).
Provide for occupational health services.
Provide funds and time for surveys, meetings, education, and development of a safety management plan. The plan should address safety and security, exposure control, emergency preparedness, waste, utilities, and equipment management.
Risk assessment
Perform safety audits and risk assessments.
Obtain MSDS and other necessary safety information.
Develop chemical inventory lists.
Identify safety needs and controls.
Training
Provide safety training for new employees, annual training for all employees, and training as needed for workers assigned to a new workstation or when a new assay/platform is implemented in the laboratory.
Plan review and record keeping
Review all audits, surveys, and accident reports to measure the effectiveness of the plan and make changes to reduce the probability of additional occupational exposures.
Evaluate and update the plan when new information is available or new hazards are introduced.
Maintain records of all surveys, accidents, and inspections and the resulting corrective actions.

To ensure that the laboratory safety policies and procedures are active and enforced, a safety officer and safety committee should be established. All sections of the laboratory should be represented on this committee. These individuals ensure that the safety program's policies, procedures, and training programs are uniform throughout the laboratory and that the laboratory is in compliance with all state and federal safety regulatory requirements. In larger organizations, the laboratory safety officer may also participate in other institutional safety-related committees. A laboratory chemical hygiene officer should also be designated to coordinate and be responsible for the laboratory's chemical waste disposal. The coordinator should evaluate hazardous chemicals based on their properties, according to national and/or regional regulations. It is essential that all employees review the safety manual, receive annual training based on the hazards and risks present in the laboratory, and understand the specific safety precautions required for each procedure or workstation.

Laboratory Hazards

The laboratory contains numerous hazards that fall into four general classes: biological, chemical, physical, and radiological. A hazard is any material, condition, or action

本书版权归John Wiley & Sons Inc.所有

that may result in physical harm or impairment of employees. The management of these hazards poses a significant challenge due to the complexity of the work and the diversity of the hazards that are present in the laboratory environment. The risk from these hazards is related to exposure levels, duration of exposure, toxicity or pathogenicity of the hazardous material, safety controls present, and other factors such as the general health or age of the laboratory worker. In general, the risk of suffering an adverse event from a laboratory hazard is decreased by minimizing the exposure to the hazard, storing only small quantities of the hazard in the laboratory, and storing hazardous materials in appropriate containers. Whenever possible, a less hazardous material should be substituted for highly toxic or dangerous chemicals.

Biological Hazards

Biological hazards include infectious agents such as bacteria, parasites, fungi, and viruses that may be transmitted through contaminated body secretions, tissue, or other materials. All clinical specimens are potentially infectious, and the isolation and culture of pathogenic microorganisms from these specimens increases the risk to the clinical microbiologist. Bacteria cause the majority of laboratory-acquired infections (LAIs), followed by viruses, rickettsia, fungi, and parasites. Today, 96% of all LAIs are caused by bacteria, viruses, and rickettsia (19). The major routes for acquiring an infection in the laboratory are from exposure to a specimen containing a potential pathogen and the procedures used to culture and identify the agent. Agents that are transmitted by aerosols cause most of the serious LAIs and include *Mycobacterium tuberculosis*, *Bordetella pertussis*, *Corynebacterium diphtheriae*, *Neisseria meningitidis*, *Bacillus anthracis*, *Brucella* spp., *Francisella tularensis*, *Burkholderia pseudomallei*, and *Yersinia pestis* (9, 20, 21). The factors that influence the risk of acquiring an infection from blood, body fluids, or OPIM are related to the quantity of specimen involved in the exposure; the concentration, prevalence, and type of pathogen in the specimen; the number and types of contact experienced by the worker; the susceptibility and behavior of the host; and the routes of exposure (e.g., percutaneous exposure, splashes to mucous membranes, splashes to intact or non-intact skin, oral ingestion, or aerosol inhalation) (19, 22, 23). Aerosols are especially problematic because they are generated by numerous procedures performed in the laboratory such as sonication, homogenization, centrifugation, mixing, pipetting, heating inoculation loops, streaking agar plates, opening lyophilized ampoules, and expelling bubbles from a syringe (9, 24, 25). Spotting organisms on a plate for MALDI-TOF MS (matrix-assisted laser desorption ionization–time of flight mass spectrometry) also poses a risk to laboratory workers (8, 26). Most select agents (see Table 25.6) are not included in the FDA-cleared organism libraries for commercially available MALDI-TOF systems. For this reason as well as safety concerns, it is recommended that MALDI-TOF not be attempted for potential agents of bioterrorism (27). For other, non-select agents such as *N. meningitidis*, plating and addition of matrix in a biological safety cabinet (BSC) should be sufficient to inactivate organisms (28). Heat inactivation prior to performance of MALDI-TOF may also be used for organisms such as *Mycobacterium* spp. It is also important for laboratory staff to be familiar with known MALDI misidentifications for select agents in order to take appropriate precautions and rule out potential biothreat agents.

Because symptoms of infection are often delayed following an exposure, the person generally cannot recall the specific event that caused the infection but only that he or she was working with the agent or was in the laboratory (19). Traditional safety guidelines have emphasized the use of safe work practices, well-designed laboratories, containment equipment, and management controls (8, 29). Today, laboratories also need to prevent unauthorized entry to the laboratory areas and removal of potential bioterrorism agents (4).

As labs are expanding their testing capacity for the SARS-CoV-2 pandemic, many institutions may have staff who have not previously worked with infectious agents handling such samples to accommodate for the increased testing volume. Following standard precautions and good laboratory practice is sufficient to protect laboratory workers from exposure to the virus. To date, there have been no reported LAIs from SARS-CoV-2 (30). Additional information can be found from the CDC and the OSHA (31, 32).

Chemical Hazards

Chemical hazards include all chemicals that may be toxic or irritating and include solids, liquids, and gases such as mercury, acetone, xylene, stains, and formaldehyde. The diversity of chemical hazards found in the clinical laboratory is as great as the biological hazards. The risk and severity of an exposure to a chemical are influenced by the amount of chemical to which one is exposed (dose), the route of exposure (i.e., inhalation, ingestion, absorption through or contact with mucous membranes, and intact/non-intact skin), the chemical properties of the compound, the susceptibility of the individual, and the duration of exposure (33).

Because containment procedures are based on the chemical hazard class, laboratory chemicals are labeled and described by their hazard classification, such as irritant, corrosive, flammable (gas, liquid, solid), poison (toxic), or carcinogen. Reactive chemicals must be segregated for storage. Acids are not stored with bases, oxidizers are not stored with reducing agents or organics, and flammables are stored in flammable-safe cabinets. Poisons or toxic compounds can cause acute or chronic symptoms

本书版权归John Wiley & Sons Inc.所有

when ingested, inhaled, or absorbed through the skin and can affect the nervous, respiratory, or reproductive systems. Carcinogens may cause malignant neoplasms in humans or animals long after exposure to the compound. Use of highly toxic chemicals or carcinogens should be restricted, and they should be handled only in a designated area by well-trained personnel.

When possible, disposable PPE should be used while handling toxic chemicals. A chemical hygiene plan (required for all laboratories) details the specific safety measures (i.e., engineering and work practice controls, PPE, exposure monitoring, waste management) required for each class of chemicals used in the laboratory.

When exposure monitoring is required, a trained industrial hygienist can measure the chemical level as the work is performed and determine whether the level exceeds the permissible exposure limit (PEL) (11, 34, 35). PELs represent the maximum concentration of a chemical to which an employee may be exposed over an 8-hour workday or 40-hour workweek (time-weighted average). PELs may also be expressed as a short-term exposure (15-minute period) or a ceiling limit not to be exceeded. These limits are set so that employees are not exposed to chemical levels that may cause acute or chronic symptoms.

Physical Hazards

Physical hazards abound in the laboratory and include such things as ergonomic issues, fire, electrical hazards, noise levels, equipment, accidents (e.g., slipping, falling, and lifting), UV light exposure, and compressed gases. Accidents often occur from overcrowding in the work area, poor lighting, poor maintenance, and lack of attention to detail by the employee. All accidents should be investigated with the intent of identifying the cause of the accident and correcting the problem. For example, back injuries are reduced by training employees on the correct method for lifting heavy objects. Falling is often caused by slippery floors, obstructed vision, or obstacles. Electrical safety relies on the proper grounding of equipment, the availability of adequate electrical outlets, and the prohibition of the use of extension cords. UV lights should be installed according to the manufacturer's instruction to avoid skin or eye injuries. Also, the laboratory should be evaluated for ergonomic problems, excessive noise, and excessive stress on employees. Workers under excessive stress tend to make more mistakes and have more frequent accidents.

Radiation Hazards

Any laboratory that performs tests using radioactive materials needs to meet the requirements of the U.S. Nuclear Regulatory Commission (NRC), including a radiation control plan. The implementation of a radiation safety program and control plan monitored by a radiation safety officer can minimize the occupational exposure to ionizing radiation from radioactive material or ionizing radiation-producing equipment (36). The degree of risk from ionizing radiation is related to the type of radiation (i.e., alpha, beta, or gamma) emitted, the quantity of radioactive material present, and the source of exposure (i.e., internal or external). Engineering and work practice controls are essential for minimizing the risk of working with radioactive material. Three factors must be considered: time, distance, and shielding. The goal is to minimize the length of exposure, maintain the greatest distance between the radioactive material and the worker, and use an effective shield (i.e., lead, Plexiglas). Work practice controls for radiation, including a dedicated area for working with radioisotopes, are similar to other laboratory hazards and include appropriate PPE (e.g., lead aprons) and monitoring badges (36). Today, most tests that were once performed by radioimmunoassay are now performed by enzyme immunoassay, so many clinical laboratories no longer handle any radiolabeled compounds.

Mental Hazards

The COVID-19 (coronavirus disease 2019) pandemic has called attention to mental health and stress that many healthcare workers, including laboratory staff, experience, though these stressors existed prior to the pandemic. Recognizing the symptoms associated with stress and burnout is important at all staffing levels. These include, but are not limited to, experiencing increased irritation, anxiety, and feelings of helplessness, as well as insomnia, lack of attention, and feeling overwhelmed (37). Staff stress and burnout not only affect the individual personnel, but can impact patient care and results.

Some commonly cited workplace stressors include increased workload, inadequate staffing, and issues with management or coworkers. In one survey, a majority of staff admitted to feeling burned out on a weekly or more frequent basis (38). Staff should be able to openly communicate about stress in the workplace, and managers should make it known that doing so would not result in any stigma or repercussions. Employees are recommended to maintain a healthy lifestyle that includes adequate sleep, healthy meals, and routine exercising, as well as prioritizing other coping strategies to deal with stress (39). Employers offering mental health benefits should make employees aware of the availability of this assistance at onboarding and at regular intervals such as annual reviews.

Standard Precautions

All laboratories should adhere to the concept of standard precautions, which states that all patients and all laboratory specimens are potentially infectious and should be handled accordingly (9, 40). This concept arose from the

本书版权归John Wiley & Sons Inc.所有

observation that infections are often unrecognized in patients. "Standard precautions" replaces earlier terms, such as "blood and body fluid precautions," "universal precautions," and "body substance precautions," found in OSHA documents (17, 41). The OSHA documents place the emphasis on blood-borne pathogens such as HIV, hepatitis B virus (HBV), and hepatitis C virus, whereas the concept of standard precautions recognizes that all infectious agents and all OPIM, except perspiration, pose risk to the healthcare worker (23).

OSHA identifies a number of practices that should be implemented to protect the worker from exposure to blood-borne pathogens, including an exposure control and risk assessment plan (9). Methods that can be implemented to minimize exposure to infectious agents shield the laboratory worker from infectious material through a set of engineering and work practice controls and the use of PPE. In addition, the OSHA regulations require that employers provide HBV vaccination, postexposure evaluation, and follow-up; communicate the hazards to employees; and maintain appropriate records (9, 22, 42). Employees who decline immunization against HBV are required to sign an HBV vaccine declination form (Appendix 25.1).

Hazard Prevention and Containment

Risk Assessment

The risk associated with handling hazardous material should be assessed, and an exposure control plan should be implemented. Rather than retrospectively analyzing problems, laboratory managers need to proactively assess risk and institute the necessary procedures to reduce the potential risk. For chemical, physical, and radiological hazards, the classification of the hazard is straightforward, and usually the risk can be determined. For biohazardous material, the assessment of risk is more difficult, is often qualitative, and is based on the pathogenicity and concentration of the agent, the infectious dose, the route of transmission, the viability of the agent in the environment, and the availability of treatment or prophylaxis (1, 8, 43).

Two lists of risk groups have been published to facilitate the assessment of risk from different microorganisms and to recommend the appropriate safety practices for handling infectious agents (8, 44). The World Health Organization (WHO) has previously listed four groups of biohazardous agents based on the level of risk to the individual and community and the availability of effective treatment and prevention (Table 25.2). The Centers for Disease Control and Prevention/National Institutes of Health (CDC/NIH) guidelines propose four biosafety levels (BSLs) and recommendations for appropriate containment practices for a list of agents known to cause LAIs. Each BSL is based on the increased risk associated with the factors listed earlier (Table 25.3). Each BSL consists of combinations of PPE, engineering and work practice controls, and laboratory design that are appropriate for work with a particular infectious agent (Table 25.4). The BSL numbers (1 to 4) imply increased occupational risk from exposure to an agent and the need for additional containment for work with that agent. A conservative approach should be used when safety information is not available for a microorganism or new laboratory procedure. Generally, routine clinical laboratories operate with BSL-2 practices or BSL-3 practices for some mycobacterial or fungal agents (8). Additional information can be found on websites listed in Appendix 25.2.

A risk assessment and exposure plan for the clinical laboratory should identify the appropriate safety practices for handling infectious material that may contain any of a variety of pathogenic microorganisms (Table 25.5) (45). Risk assessment must take into account the agent, the

Table 25.2 WHO classification of microorganisms by risk group[a]

Risk group	Characterization
1	Low or no individual and community risk. Unlikely to cause human disease (e.g., tobacco mosaic virus).
2	Moderate individual and low community risk. Unlikely to cause serious disease or be transmitted. Effective treatment and prevention available (e.g., *Pseudomonas aeruginosa*).
3	High individual and low community risk. Causes serious infections but not readily transmitted. Effective treatment and prevention usually available (e.g., HIV-1).
4	High individual and high community risk. Causes serious human disease and readily transmitted. No effective treatment or prevention available. (e.g., Ebola virus).

[a] From reference 44.

Table 25.3 CDC/NIH-recommended biosafety levels for infectious agents[a]

BSL	Characterization
1	Well-characterized agents not known to consistently cause disease in healthy adult humans. Minimal potential hazard to laboratory personnel and the environment (e.g., *Escherichia coli*)
2	Agents associated with human disease of moderate potential hazard to personnel and the environment (e.g., HIV-1)
3	Indigenous or exotic agents that cause serious or potentially lethal disease as a result of exposure by the inhalation route (e.g., *Bacillus anthracis*)
4	Dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease (e.g., variola virus)

[a] From reference 8.

本书版权归John Wiley & Sons Inc.所有

Table 25.4 Laboratory biosafety level criteria[a]

BSL	Practices	Safety equipment and facilities
1	Standard microbiological practices Controlled access Sharps precautions Display biohazard signs	PPE (coats, gloves) as needed
2	BSL-1 practices Restricted access Staff trained with pathogens Safety manual available	Class I or II BSC used for specimen processing and work producing aerosols or splashes: PPE (coats, gloves, eyewear/face shields) as needed; self-closing laboratory doors; eyewash station available
3	BSL-2 practices Consider baseline serum for all at-risk personnel	BSL-2 equipment/facilities and BSC (class II or III) used for work with all specimens and cultures; PPE (gowns, masks) as needed; negative pressure airflow; exhausted air not recirculated; decontamination (e.g., autoclave) in laboratory
4	BSL-3 practices Clothing change before entering Shower on exit Decontaminate all waste on exit	Class III BSC or class II BSC in combination with full-body, air-supplied, positive pressure personnel suit; anteroom for clothing change/shower; specialized ventilation and decontamination system

[a] From reference 8.

Table 25.5 Risk assessment and exposure control plan for a clinical microbiology laboratory[a]

	Exposure risk from:		PPE[b]			Engineering controls[c]	
Laboratory task	Blood and body fluids	Cultured biologic agents	Gloves	Lab coats/ gowns	Face/splash shields	BSC	Sharps containers available[d]
Laboratory General							
Supplies inventory	Low			Coat			
Clerical: computer entry, telephones, records, etc.	Low		P	Coat			
Instrument maintenance:							
Parts contaminated	High	Variable	R	Gown			
Parts not contaminated	Low	Variable	D	Coat			
Surface decontamination	Low	Variable	R	Coat			
Waste disposal	High	Variable	R	Gown	A(D)		Sharps
Bacteriology[e]							
Specimen processing	High	BSL-2	R	Coat		R	Sharps
Subculture blood culture bottles	High	BSL-2	R	Coat	A[f]	A[f]	Needles
Subculture colonies or broth cultures	Low	BSL-2[e]		Coat			Sharps
Prepare, fix, stain, and read slides	Low	BSL-2		Coat			Slides
Identification tests and antimicrobial susceptibility testing	Low	BSL-2		Coat			Sharps
Mycology and Mycobacteriology[e]							
Specimen processing	High	BSL-2/3	R	Gown	R[e]		Sharps
Prepare smears, wet mounts; fix slides	High	BSL-2/3	R	Gown	R		Slides
Read wet mounts from specimens	High	BSL-2/3	R	Coat			Slides
Read wet mounts from cultures	Low	BSL-2/3	R	Coat			Slides
Examine sealed cultures	Low	BSL-2/3[g]		Coat			

本书版权归John Wiley & Sons Inc.所有

Table 25.5 *(continued)*

Laboratory task	Exposure risk from: Blood and body fluids	Exposure risk from: Cultured biologic agents	PPE[b] Gloves	PPE[b] Lab coats/ gowns	PPE[b] Face/splash shields	Engineering controls[c] BSC	Engineering controls[c] Sharps containers available[d]
Stain fixed smears, read	Low			Coat			Slides
Handle yeast cultures, smears, and fixed slides	Low	BSL-2		Coat		D	Slides
Handle molds and mycobacteriology cultures	Low	BSL-2/3[h]	R	Gown		R[e]	Sharps
Virology[i]							
Specimen processing	High	BSL-2	R	Coat	R		Sharps
Feed and manipulate uninoculated cells	Low			Coat			Pipettes
Read cells for cytopathic effect	Low	BSL-2		Coat			
Feed and manipulate inoculated cells	High	BSL-2	R	Coat		R	Pipettes
Perform identification tests	High	BSL-2	R	Coat		D	Sharps
Stain fixed slides, read	Low			Coat			Slides
Parasitology							
Concentrate fecal specimens, smears, wet mounts	Low	BSL-2	R	Coat			Pipettes, sticks
Read fecal wet mounts	Low	BSL-2	R	Coat			Slides
Prepare blood smears; fix slides	High	BSL-2	R	Coat	A		Slides
Stain and read slides	Low			Coat			Slides
Molecular testing							
Specimen processing	High	BSL-2/3	R	Coat	A[j]	A[j]	Pipettes
Cultured microorganism	Low	BSL-2	D	Coat		R	Sharps
		BSL-3	R	Gown		R[k]	Sharps
Serology							
Manipulate serum	High	BSL-2	R	Gown	A		Pipettes
Arrange tubes; prepare and dispense reagents	Low			Coat			
Mix serum and reagents; read and discard tests	High	BSL-2	R	Gown	A[j]	A[j]	Pipettes

[a] Adapted from reference 45. Abbreviations: R, required; D, discretionary; P, prohibited; A, one of the required alternatives.
[b] Remove PPE when leaving the laboratory. Gowns must have a solid front and be impervious to liquid.
[c] Recapping of needles is prohibited. Carry tubes in racks or use plastic tubes. Plan each task to minimize known hazards. Wash hands before leaving the laboratory.
[d] Sharps include needles, scalpels, pipettes, sticks, syringes, slides, plastic loops, and coverslips.
[e] Requires surveillance and action plan for occasional isolation of BSL-3 organism (e.g., *Brucella* spp., *Francisella* spp., *Mycobacterium* spp., and systemic fungi), especially when plates are held more than 3 days. *Mycobacterium tuberculosis* requires the use of a safety centrifuge, a BSC, and a HEPA-filtered mask or respirator.
[f] Use a BSC or acrylic splash shield.
[g] Requires a contingency plan for breakage of culture containers.
[h] Mycobacteria other than tuberculosis can be handled at BSL-2; however, use BSL-3 practices because most manipulations precede organism identification.
[i] Special precautions for BSL-4 agents (e.g., hemorrhagic fever virus, smallpox) should be arranged through CDC's emergency number (770-488-7100).
[j] Vortexing or other splatter-generating steps require use of a BSC or safety shield.
[k] Requires BSL-3 practices if there is potential for aerosols.

host, and the work activity in the development of a comprehensive safety plan (1). Management must monitor the plan, document accidents in writing, and make adjustments based on accidental exposures to infectious agents and new information. Laboratory accidents should be discussed at the quality assurance or safety committee meeting (preferably quarterly but no less than yearly) and immediately with the staff in the section where the accident occurred. The accident report and corrective action are documented in the minutes of the committee meeting. Common safety mistakes or compliance issues are listed in Appendix 25.3.

本书版权归John Wiley & Sons Inc.所有

Laboratories that use or store Select Agents (Table 25.6) (46) under BSL-2, -3, or -4 practices must address the following security and safety concerns:

- Risk and threat assessment
- Facility security plans
- Physical security
- Security of data and electronic technology systems
- Security policies for personnel
- Access controls to the laboratory
- Procedures for agent inventory and accountability
- Shipping, transfer, and receiving of select agents
- Emergency response plans
- Reporting of incidents, unintentional injuries, and security breaches

Table 25.6 Select agents and toxins[a,b]

Bacteria
Bacillus anthracis (including Pasteur strain) and *Bacillus cereus* Biovar *anthracis*
Brucella suis, melitensis, and *abortus*
Burkholderia mallei and *B. pseudomallei*
Clostridium species that produce botulinum neurotoxin
Francisella tularensis
Yersinia pestis
Rickettsiae
Coxiella burnetii
Rickettsia prowazekii
Viruses
Crimean-Congo hemorrhagic fever virus
Eastern equine encephalitis virus
Ebola virus
Equine morbillivirus (Hendra, Nipah)
Kyasanur Forest disease virus
Lassa fever virus
Lujo virus
Marburg virus
Monkeypox virus
Omsk hemorrhagic fever virus
Reconstructed 1918 influenza virus
Rift Valley fever virus
SARS-associated coronavirus (SARS-CoV)
South American hemorrhagic fever viruses
Tick-borne encephalitis complex viruses
Variola major and minor virus (smallpox virus)
Venezuelan equine encephalitis virus
Toxins
Abrin
Botulinum toxins
Conotoxins
Diacetoxyscirpenol
Ricin
Saxitoxin
Shigatoxin
Staphylococcal enterotoxins
Tetrodotoxin
T-2 toxin

[a] From reference 46.
[b] Human and overlap select agents and toxins only; exclusive veterinary and plant select agents not listed.

The Select Agents plan must be part of the daily operation of the laboratory, and all employees must be knowledgeable about the plan (4). For security of select agents areas and public safety, access to the laboratory should be limited and restricted to individuals who have a legitimate purpose for entering the work area. Laboratory entrances should be locked by keypads, keys, or identification card keys. Laboratory employees should continuously monitor entrances that remain open. The laboratory should have a policy that defines who may visit and a procedure for removing unauthorized persons. Visitors and service workers should sign an entry log, be issued an identification badge with an expiration date, wear a laboratory coat, and be accompanied by a laboratory employee. Laboratory supervisors should ensure that all visitors and service workers understand the laboratory's security and safety requirements, safety signage, and areas that are posted off-limits to visitors.

Most clinical laboratories serve as sentinel laboratories in the national Laboratory Response Network (LRN). The primary responsibility of a sentinel laboratory is to rule out and refer suspected select agents to the nearest LRN reference laboratory (usually a state health laboratory) or a federal-level laboratory, depending on the suspected agent. Laboratory personnel should be familiar with the morphological, cultural, and identification characteristics of certain select agents that might be encountered in clinical specimens. The laboratory should notify the institutional infection control or epidemiology personnel who are responsible for assessing the situation and notify local or state public health officials.

Maintenance workers and cleaning staff must also understand the laboratory's security and safety procedures, sign the entry log, and, ideally, perform their tasks when laboratory employees are present. The laboratory supervisor should instruct the maintenance and cleaning staff on the restricted areas of the laboratory (e.g., mycobacteriology laboratory) and precisely define their duties (e.g., do not handle biohazardous material). When work is required in the restricted areas, a laboratory worker should escort or monitor the person.

Handwashing

Handwashing is the most important procedure to reduce the duration of exposure to an infectious agent or chemical, prevent dissemination of an infectious agent, and reduce overall infection rates in a healthcare facility. Hand contamination occurs during manipulation of

本书版权归John Wiley & Sons Inc.所有

specimens and contact with work surfaces, telephones, and equipment. Laboratory personnel should wash their hands:

- Immediately after removing gloves
- After obvious contamination
- After completion of work
- Before leaving the laboratory
- Before hand contact with non-intact skin, eyes, or mucous membranes

Handwashing sinks should be located at each entry and exit door, and ideally the faucet should be operated by a knee or foot control. If these controls are not available, the faucet should be turned on and off using a paper towel. Handwashing should be performed using a soap or antiseptic compound, starting at the wrist area and extending down between the fingers and around and under the fingernails. Hands should be rinsed from the wrists downward (47). Recently, the CDC recommended that in addition to traditional soap and water handwashing, healthcare personnel can also use alcohol-based gels (Table 25.7) (48).

Barrier Protection

PPE shields the individual from contact with a particular hazard. OSHA standards require that PPE shall be provided, used, and maintained for all hazards found in the workplace, including biological, environmental, chemical, and radioactive compounds and mechanical irritants capable of causing injury or illness through absorption, inhalation, or physical contact. Employees must be trained in the appropriate use of PPE for a specific task, the limitations of PPE, and procedures for maintaining, storing, and disposing of PPE.

Gloves. Gloves protect the wearer from exposure to potentially infectious material and other hazardous material and are available in materials designed for specific tasks. Gloves must be provided by the employer and should be of the proper size and appropriate material for the task. Gloves are available in wrist, elbow, and shoulder length. Thin latex, vinyl, or nitrile gloves offer protection from exposure to potentially infectious material and should be changed frequently. Because of latex hypersensitivity in some workers, only powder-free latex gloves should be used, or better yet, gloves should be made of nitrile, polyethylene, or another material. The prevalence of latex allergy in healthcare workers ranges from 6 to 16% and usually presents as a type of allergic reaction (e.g., skin rashes; hives; flushing; itching; nasal, eye, or sinus symptoms; asthma; and rarely, anaphylaxis). While removal of latex products from the workplace is the final solution, other exposure control measures include education of new employees on latex allergies, screening high-risk employees for latex allergy symptoms, and frequent cleaning and changing of ventilation filters in latex use areas. When an employee suffers from the more serious type I hypersensitivity to latex, latex cannot be used in the employee's work area, which should be posted as "latex free."

When working with chemicals, the gloves should be of a material known to resist the particular chemicals. Generally the material will be neoprene, nitrile, or a butyl rubber. General-purpose utility gloves should be used for housekeeping chores. Insulated gloves are available for handling hot or cold items. Puncture-resistant gloves

Table 25.7 Characteristics of hand-hygiene antiseptic agents[a]

	Bacteria						
Group	**GP**	**GN**	**Mycobacteria**	**Fungi**	**Viruses**	**Speed of action**	**Comments**
Alcohols	+++	+++	+++	+++	+++	F	Optimum concentration 60–95%; no persistent activity
Chlorhexidine (2% and 4% aqueous)	+++	++	+	+	+++	I	Persistent activity; rare allergic reactions
Iodine compounds	+++	+++	+++	++	+++	I	Causes skin burn; usually too irritating for hands
Iodophores	+++	+++	+	++	++	I	Less irritating than iodine
Phenol derivatives	+++	+	+	+	+	I	Neutralized by nonionic detergents
Triclosan[b]	+++	++	+	–	+++	I	Acceptability on hands varies
Quaternary ammonium compounds	+	++	–	–	+	S	Used only in combination with alcohols; ecologic concerns

[a] From reference 48. +++, Excellent; ++, good, but does not include entire bacterial spectrum; +, fair; –, no activity or not sufficient; F, fast; I, intermediate; S, slow; GP, Gram positive; GN, Gram negative.

[b] A polychlorophenoxyphenol.

本书版权归John Wiley & Sons Inc.所有

should be used in the autopsy suite or when handling scalpels or other sharp objects.

Protective clothing. Laboratory workers should wear fully closed long-sleeved coats or gowns that extend below the level of the workbench. When there is a potential for splashing or spraying, the material must be fluid resistant. Fluid-proof clothing (plastic or plastic lined) must be worn when there is the potential for soaking by infectious material. When handling chemicals, clothing must be composed of a material that is resistant to the particular chemical. Laboratory workers should not wear laboratory clothing out of the laboratory. All protective clothing should be changed immediately when contaminated to prevent the potentially infectious material or chemical from contacting the skin. Coats and gowns should not be taken home for cleaning but should be laundered by the institution. When handling highly toxic compounds, complete body suits should be worn.

Face and eye protection. Face and eye protection should be used when splashes or sprays of infectious material or chemicals may occur. Face and eye protection equipment includes goggles, face shields, and splash guards. Face shields provide the best protection for the entire face and neck. Splash guards provide an alternative method for face and eye protection. If only goggles are worn, the user should also wear an appropriate mask to prevent contamination of mucous membranes. Hazardous materials such as corrosives should always be manipulated behind splash guards or while wearing appropriate PPE.

Engineering Controls

Engineering controls are those that involve making changes to the work environment to reduce work-related hazards. These types of controls are preferred over all others because they make permanent changes that reduce exposure to hazards and do not rely on worker behavior. By reducing a hazard in the workplace, engineering controls can be the most effective solutions for laboratories to implement. These controls include mechanical pipettes, bench tops impervious to liquids and chemicals, biohazard bags, centrifuge safety cups, eyewash stations, ventilation systems, BSCs and fume hoods, plasticware, and plastic collection devices (e.g., vacutainers, hematocrit tubes) (49). An OSHA standard requires that safety needle devices or needleless systems be used whenever possible (50, 51). All hazardous chemicals should be stored below eye level and transported in safety carriers. Incompatible chemicals should be stored apart, and flammables should be stored in a safety canister and a flame-resistant cabinet. The maximum quantity of flammable material that can be stored in a cabinet is defined by the manufacturer (11). Flammables requiring refrigeration can only be stored in an explosion-proof refrigerator. Compressed gas cylinders must be moved with the valve safety cover in place and secured to a handcart. When stationary, the cylinder must be secured upright with bottom and top restraints.

Work Practices

Work practices are procedures for safe and proper work that are used to reduce the duration, frequency, or intensity of exposure to a hazard. These controls need to be understood and followed by all who work in the laboratory. These practices include not allowing mouth pipetting and selecting less hazardous chemicals for a specific procedure. Wearing open-toed shoes or sandals should not be allowed in the laboratory, to prevent accidental spillage on bare skin. Movements that bring the hand to the mouth, eyes, or mucous membranes should be discouraged. Therefore, employees should not eat, drink, apply cosmetics or contact lenses, etc., in the laboratory. Visitors should be discouraged or accompanied by an employee.

Respiratory Protection

Respiratory devices are available to prevent inhalation of chemical dust or fumes and infectious aerosols. The type of mask used depends on the specific hazard. For example, a properly fitted N95 mask is employed for protection against aerosolized *M. tuberculosis* (9). A chemical fume mask employs cartridges that are designed to reduce exposure to a particular chemical, but the cartridge must be replaced periodically. A self-contained breathing apparatus offers the greatest degree of protection and is used when toxic levels are high or the danger is unknown (11).

Immunization

The current CDC/APIC (Association for Professionals in Infection Control and Epidemiology) guidelines on immunization of healthcare workers, including laboratory personnel, provide recommendations, on the basis of documented healthcare-related transmission, for agents for which there is substantial risk of acquisition or transmission. These include hepatitis B, influenza, measles, mumps, rubella, pertussis, and varicella (52, 53) (Table 25.8). The recommendations for vaccination of healthcare personnel are represented by two categories: (i) diseases for which routine vaccination or documentation of immunity is recommended because of risks to personnel in their work settings and, should a healthcare worker become infected, to the patients they serve; and (ii) diseases for which vaccination of personnel might be indicated in certain circumstances. Vaccines recommended in the first category are hepatitis B; seasonal influenza; measles, mumps, and rubella; pertussis; and varicella vaccines. Vaccines in the second category are COVID-19, meningococcal, typhoid, and polio vaccines.

本书版权归John Wiley & Sons Inc.所有

Table 25.8 Vaccinations and schedule for healthcare personnel[a,b]

Name	Primary schedule/booster(s)	Indications
Vaccinations recommended for all healthcare personnel		
Hepatitis B recombinant vaccine	Two doses 4 weeks apart; third dose 5 months after second; booster doses not necessary	Personnel at risk for exposure to blood or body fluids
Influenza vaccine (TIV and LAIV)	Annual vaccination with current seasonal vaccine	All healthcare personnel
Measles live-virus vaccine	Two doses at least 28 days apart	Recommended for all personnel who lack presumptive evidence of immunity[c]; should be considered for those born before 1957
Mumps live-virus vaccine	Two doses at least 28 days apart	Recommended for all personnel who lack presumptive evidence of immunity[d]; should be considered for those born before 1957
Rubella live-virus vaccine	Two doses at least 28 days apart	Recommended for all personnel who lack presumptive evidence of immunity[e]
Tetanus and diphtheria (toxoids) and acellular pertussis (Tdap)	One dose regardless of last Td; after Tdap, receive Td for routine booster every 10 years	All healthcare personnel
Varicella-zoster virus live-virus vaccine	Two doses 4 to 8 weeks apart if aged greater than 12 years	All healthcare personnel who do not have evidence of immunity[f]
Other immunologics that might be indicated in certain circumstances for healthcare personnel		
Quadrivalent meningococcal conjugate vaccine (ages 19–54 years); quadrivalent meningococcal polysaccharide vaccine (age ≥ 55 years)	One dose; booster dose in 5 years if person remains at increased risk	Microbiologists who might be routinely exposed to isolates of *Neisseria meningitidis*
Typhoid vaccine	IM: one dose, booster every 2 years; oral: four doses on alternate days, revaccination with entire four-dose series every 5 years	Microbiologists who frequently work with *Salmonella enterica* serovar Typhi
Inactivated poliovirus vaccine (IPV)	If unvaccinated, two doses 4 to 8 weeks apart; third dose 6 to 12 months after second dose	Healthcare personnel with exposure to patients who might be excreting polioviruses
COVID-19 (SARS-CoV-2) vaccine	IM: one or two doses depending on manufacturer recommendations	All healthcare personnel are recommended to get vaccinated against COVID-19

[a] From reference 53 and https://www.cdc.gov/vaccines/adults/rec-vac/index.html (accessed 9 October 2023).
[b] Institutions may require a signed declination (example in Appendix 25.1) for recommended and required vaccines.
[c] Written documentation of vaccination with two doses of live measles or MMR vaccine administered greater than 28 days apart or laboratory evidence of measles immunity or laboratory confirmation of measles disease or birth before 1957.
[d] Written documentation of vaccination with two doses of live mumps or MMR vaccine administered greater than 28 days apart or laboratory evidence of measles immunity or laboratory confirmation of measles disease or birth before 1957.
[e] Written documentation of vaccination with one dose of live rubella or MMR vaccine administered greater than 28 days apart or laboratory evidence of measles immunity or laboratory confirmation of measles disease or birth before 1957.
[f] Evidence of immunity is defined as written documentation of vaccination with two doses of varicella vaccine or laboratory evidence of immunity or laboratory confirmation of disease or diagnosis/verification of varicella disease by a healthcare provider.

Warning Signs and Labels

Warning signs and labels are designed to provide a universal policy to alert visitors and employees to potential laboratory hazards and hazardous areas in the laboratory. A comprehensive warning labeling system should be implemented to identify contaminated objects or hazardous materials. OSHA-specified signage should be used whenever applicable (14, 16, 18). The color of the sign identifies the level of risk: (i) danger (red, white, and black), (ii) caution (yellow and black), or (iii) safety instruction (green and white) (14). Containers of hazardous reagents, radionuclides, chemicals, and waste must be labeled with the chemical name and appropriate hazard label (e.g., flammable, corrosive, carcinogen, irritant).

Biological Safety Cabinets and Chemical Fume Hoods

Chemical fume hoods should be used when there is risk of exposure to hazardous fumes or splashes while preparing or dispensing chemical solutions. Airflow is generally controlled by a movable sash and should be in the range of 80 to 120 feet per minute (11, 18). Objects in the hood should not obstruct the airflow or the workspace. Chemical fume hoods are certified annually.

Biological hazards are best contained within a class IIA or class IIB BSC. BSCs are the most important containment equipment in the microbiology laboratory. Class III cabinets are used with infectious agents requiring BSL-3 or -4 containment. BSCs operate at a negative air pressure, with

本书版权归John Wiley & Sons Inc.所有

air passing through a HEPA filter. The vertical airflow serves as a barrier between the cabinet and user. BSCs are certified annually. More detailed information on the selection and use of BSCs can be found in Appendix 25.2 and references 8, 9, 54.

Sterilization and Decontamination

When discussing germicides, sterilants, disinfectants, and decontamination, it is important to understand the differences between the terms (9, 47, 49). A germicide is a substance that kills pathogenic organisms on inanimate surfaces. Disinfectants destroy all microorganisms, but not necessarily their spores, on inanimate surfaces. Sterilants are agents that kill all microbial life, including spores, on inanimate surfaces. Prions (abnormal host proteins) are not covered by these definitions.

Decontamination is a procedure that eliminates or reduces microbial or toxic agents to a safe level with respect to the transmission of infection or other adverse effects. Routine decontamination of the work environment is usually performed with disinfectants (Table 25.9). It is important that the manufacturer's instructions for preparation and use be followed carefully. The selection of a disinfectant depends on the degree of microbial killing required, the effectiveness against an extended spectrum of pathogens, compatibility with the surface or device being decontaminated, toxicity, residue activity, and odor. Disinfectants can be hazardous compounds when not used properly (Table 25.9). No single product is adequate for all decontamination purposes. Appropriate PPE (i.e., gloves, impervious gowns, eye protection, masks) should be worn when cleaning and decontaminating equipment. Alcohol should not be used in a poorly ventilated area or near flames, and corrosive sodium hypochlorite solutions should not be used on metals.

Prions, the causative agents of Creutzfeldt-Jacob disease and transmissible spongiform encephalopathies, are resistant to standard disinfection and sterilization procedures (9, 49, 55, 56). The disinfection procedures for high-risk specimens (central nervous system tissue), medium-risk specimens (cerebrospinal fluid, lymph node, spleen, pituitary gland, and tonsil), and low-risk specimens (bone marrow, liver, lung, thymus, and kidney) or equipment contaminated with these specimens differ according to the level of risk (9, 56). Devices or material contaminated with high-risk tissue should be discarded or decontaminated by steam sterilization at 121°C for 1 hour or soaked in 1 N NaOH for 1 hour or in 0.5% sodium hypochlorite (2% free chlorine) for 2 hours before cleaning and sterilization by conventional means (9). Conventional heat, chemical, or gas sterilization or high-level disinfection can sterilize devices contaminated by medium- or low-risk specimens. Formaldehyde (3.7 to 4.0%)-fixed brain tissue (0.5 mm thick) is soaked in 95–100% formic acid for 1 hour followed by immersion in fresh 4% formaldehyde for 48 hours before histological slides are prepared for examination.

Table 25.9 Activity levels and hazards of selected germicides[a]

Procedure/product	Aqueous concentration	Activity level	Hazards
Sterilization			
Glutaraldehyde	Variable	NA	Dermatitis, toxic
Hydrogen peroxide	6–30%	NA	Irritant
Formaldehyde	6–8%	NA	Irritant, toxic, sensitization
Chlorine dioxide	Variable	NA	Irritant, gas toxic
Peracetic acid	Variable	NA	Irritant
Disinfection			
Glutaraldehyde	Variable	High to intermediate	Dermatitis, toxic
Hydrogen peroxide	3–6%	High to intermediate	Irritant
Formaldehyde	1–8%	High to low	Irritant, toxic, sensitization
Chlorine dioxide	Variable	High	Irritant, gas toxic
Peracetic acid	Variable	High	Irritant
Chlorine compounds	500–5,000 mg/liter free available chlorine	Intermediate	Gas toxic, irritant
Alcohols	Ethyl, isopropyl: 70%	Intermediate	Toxic (isopropyl)
Phenolic compounds	0.5–3%	Intermediate to low	Leukoderma, depigmentation
Iodophor compounds	40–50 mg/liter free iodine; up to 10,000 mg/liter available iodine	Intermediate to low	Skin irritation
Quaternary ammonium compounds	0.1–0.2%	Low	Dermatitis, sensitization

[a] From references 9, 47, and 48. NA, not available.

本书版权归John Wiley & Sons Inc.所有

Spill Management

Biological

The management of biohazardous spills in the clinical laboratory must account for the specific infectious agent, the volume of infectious material spilled, and the presence of aerosols. Spills involving BSL-3 agents are serious because aerosols can transmit these agents. Occupants should hold their breath, evacuate the area immediately, close the doors, and not reenter the area for 30 to 60 minutes (9, 57). When breakage occurs in a centrifuge, the equipment must remain closed for at least 30 minutes before decontamination is undertaken. A tuberculocidal disinfectant should be used for decontamination (49). A low-level disinfectant such as a quaternary ammonium compound should not be used. Additional factors that influence decontamination of the spill site include the type of infectious material (blood, culture medium), the concentration and virulence of the infectious agent, the protein content of the material, and the spill surface (porous or fluid resistant). Initially, spills should be absorbed with paper towels, gauze pads, or commercial absorbents such as granular or silica gel absorbents.

Generally, the spill cleanup should be performed by the individual who accidentally spilled the infectious material or by personnel specifically trained in the cleanup of biohazardous materials. Appropriate protective equipment must be used in decontaminating spills involving BSL-2 or BSL-3 agents. The PPE includes disposable gloves (heavyweight and puncture resistant), fluid-impermeable shoe covers, coats or gowns with long sleeves, and facial protection. When the spill involves an agent requiring BSL-3 practices, a respirator or HEPA-filtered mask should be used. In this situation it is usually best to call the spill emergency response team, which is trained to handle this type of spill.

Any broken glass in the spill area should be removed and discarded without contact with the hands. This is accomplished with rigid cardboard, tongs, forceps, hemostats, or a plastic scoop (dustpan). Glass is discarded into a puncture-resistant container, and other contaminated material is discarded into a biohazardous waste container.

After the absorbent material is discarded, the spill site can be cleaned with an aqueous detergent solution to dilute any remaining infectious material and to remove excess protein. A tuberculocidal disinfectant should be used that remains on the site for 20 minutes. Any remaining disinfectant is then absorbed with absorbent material, and the area is rinsed with water and dried.

When spills occur in a BSC, do not turn off the cabinet fan. Minor spills can be absorbed with absorbent paper, and the area can be decontaminated with a disinfectant. If the infectious material has flowed into the grille, all items in the cabinet should be wiped with a disinfectant and removed. The drain valve should be closed, and disinfectant should be poured onto the surface and through the grille into the drain pan. You should allow 20 minutes of contact time with the disinfectant and then absorb the disinfectant with paper towels. Attach a hose to the drain valve and drain into a container with disinfectant. Remove the grille and rinse the drain pan with water. For major spills involving BSL-3 agents, a service consultant should be contacted for decontamination.

All materials necessary for the cleanup of a biohazardous spill should be assembled and stored as a biohazard spill kit (Appendix 25.4). The kit should contain an appropriate disinfectant (e.g., 10% household bleach), absorbent material (e.g., paper towels, gauze pads, and granular material such as BioZorb for large spills), PPE (e.g., puncture-resistant utility gloves, water-impermeable shoe coverings, gown, mask, face shield, or eyewear), and autoclavable dustpan, tongs or forceps, plastic scoop and pusher, and bags. For BSL-3 agents a full-face respirator or HEPA-filtered mask should be available. The biohazard spill kit can be stored in a puncture-resistant biohazardous waste container. Examples of spill cleanup procedures may be found in various guidelines (8, 9, 49, 57) and Appendix 25.5. Following the spill cleanup, a report should be completed and submitted to the safety committee.

Chemical

The laboratory should have adequate spill response equipment readily available as a chemical spill kit (14). In the event of a chemical spill or leak, an initial determination of the need for an evacuation is made based on the immediate danger to life or health or when employees experience severe discomfort. Any or all of the following conditions usually warrant an evacuation:

- Injured or ailing personnel
- Symptoms of irritation reported by employees
- Large-volume spill
- Flammable or explosive material spilled
- Carcinogen spilled
- Presence of strong odors

When an evacuation is required, close off the area, notify employees in the immediate vicinity of the spill, and report the situation to the emergency response team. Provide the location, nature of the spill, personnel injured or trapped, and hazard involved. Do not attempt to rescue patients or employees if your life or health may be endangered.

For minor spills (not involving flammables, explosives, or carcinogens), contain the spill, close off the spill area, and contact the emergency response team. An example of a chemical spill cleanup procedure for minor spills is

本书版权归John Wiley & Sons Inc.所有

shown in Appendix 25.6. A trained person should clean up the spill using appropriate PPE (gloves, gowns, and shoe covers resistant to the chemical, plus a face shield). Contain the spill with spill pads, pillows, or socks. Clean the spill using approved absorbents and neutralizing agents. Package the waste appropriately for pickup, labeling the container with the substance, date, and amount of material. As with biological spills, the response is dependent on the chemical hazard and volume of the spill. Prepare a spill report and submit it to the safety committee. The material safety data sheets (MSDSs) contain information on the hazard classification; appropriate PPE; symptoms arising from exposure; and instructions for the safe handling, disposal, and cleanup of laboratory chemicals. OSHA requires that MSDSs for all laboratory chemicals be readily available to all employees. Emergency aids such as eyewash stations and an emergency shower should be available in locations in which caustic and corrosive chemicals are used and in which the possibility of a large spill exists.

Fire Safety

While proper procedures and training can minimize the chances of an accidental fire, laboratory workers should still be prepared to deal with a fire emergency should one occur. Laboratories should have a written emergency plan and ensure that workers are trained. A training program should be provided for new employees and updates provided to current employees as needed. The program should include recognition and evaluation of fire hazards, planning to reduce the risk of fire, and all actions to take when a fire occurs (14).

Disaster Preparedness

OSHA and the Centers for Medicare and Medicaid Services (CMS) require an emergency preparedness plan, including for potential natural disasters such as earthquakes, hurricanes, and winter storms that may affect laboratory operations. Specific guidelines for potential natural disasters and severe weather conditions are available on the OSHA website (www.osha.gov). As part of the emergency preparedness plan, institutions are required by CMS to have an organized strategy for staffing and scheduling to maintain continuity of care during potentially disruptive events. This may also include a recovery plan when the timing allows for resumption of normal operations. Emergency preparedness plans should be reviewed and updated at least every 2 years.

Waste Management

The laboratory is a major generator of chemical and biohazardous waste in the healthcare facility. Procedures for the handling of chemical waste are well defined because the hazardous substance is usually identifiable. However, medical or infectious wastes are not well defined and include categories such as contaminated sharps, cultures and stocks of infectious agents, blood and body fluids, and pathological waste (58, 59). For effective and efficient management of infectious wastes, a comprehensive management plan is essential to ensure the safety of the employees handling the waste, compliance with the various regulatory requirements, meeting the standards of The Joint Commission and the guidelines of other professional groups such as the Clinical and Laboratory Standards Institute (CLSI), and implementation of cost-effective strategies for waste disposal. The management plan should include contingencies for potential weather or disaster-related events that have the potential to disrupt regularly scheduled disposal.

Regulatory Oversight

There are numerous federal, state, and local regulations governing the management of biohazardous waste as follows.

Federal regulations:

- OSHA's Bloodborne Pathogen Standard (17): Applies to the handling and packaging of regulated waste and the implementation of procedures to protect employees against potential exposure to infectious medical waste.
- Department of Transportation (DOT) (60, 61): Sets requirements for transport of hazardous materials and regulated medical waste.

Guidelines and standards:

- CDC/NIH (8): Management of infectious waste.
- CLSI (58): Management of waste generated by a clinical laboratory.
- The Joint Commission (62): Requires a waste management plan for the institution that is in compliance with all federal, state, and local regulations.
- State and local regulations: Many state and local jurisdictions have passed regulations governing the handling, treatment, and disposal of biohazardous waste.

Management Program

The laboratory's waste management plan should be part of the overall facility plan and must comply with the numerous federal, state, and local regulations. Most plans address the following elements.

Identification of hazardous waste. Although no generally acceptable definition of medical waste is available, there are categories of waste that are considered potentially infectious, namely human blood, body substances, and

本书版权归John Wiley & Sons Inc.所有

blood products; contaminated sharps; cultures and stocks of microbial agents; contaminated laboratory waste; PPE grossly contaminated with blood, body fluids, or microbiological cultures; and pathological waste (8, 9, 17, 58, 63).

Segregation. Knowledgeable personnel should segregate waste into designated categories (i.e., chemical, routine trash, radiological, and infectious) at the point of generation to reduce the cost of disposal and to protect employees and others from exposure to hazardous material.

Packaging and labeling. Appropriate containment of hazardous material is the key to minimizing personnel and public exposure. Chemical and radioactive waste is separated and handled differently from other regulated medical waste. Containers for liquids are leakproof. All containers must have secure closures and maintain their integrity throughout the handling and transportation process. Containers must comply with the OSHA requirements for the category and volume of waste and treatment, transportation, labeling, and disposal method. For example, sharps must be placed in impervious, rigid, leakproof, color-coded, puncture-resistant containers with secure lids. Other medical waste may be placed in containers that are leakproof and labeled or color coded as to hazard and have secure closures.

Storage. All waste should be treated as soon as possible. The waste storage area should be posted as to the hazard, be sited near the treatment area or loading dock for off-site treatment, and maintain a temperature and duration of storage that prevent spoilage. Access should be limited to authorized personnel.

Transport. Waste is transported in labeled and leakproof containers or carts appropriate for the hazard. When shipped to an off-site treatment facility, the containers must meet the specifications established by the DOT. Transportation containers or carts should be routinely disinfected.

Treatment and disposal. The treatment and disposal of waste must comply with all federal, state, and local regulations. Most institutions contract with companies licensed to treat and dispose of hazardous waste. A number of waste treatment techniques and disposal methods are available for organizations that produce a small amount of waste (58, 63), but they must meet all regulatory requirements.

Contingency planning. The waste management plan should include a written plan for alternative treatment and disposal in the event of the failure of the normal waste management process. This plan must provide for increased storage or include an agreement with another generator to handle the waste in an emergency.

Training. Employee training must comply with OSHA's requirements and should include exposure risk information, safety policies, procedures for handling waste, required PPE, and the duties and responsibilities of the position. Training occurs annually for all employees, immediately for new employees, and before workers assume new duties or tasks.

Packaging and Shipping Infectious Substances

A complex and confusing set of national and international guidelines and regulations governs the packing and shipment of clinical specimens and cultures of microorganisms (44, 60, 64, 65). The most widely recognized, copied, and accepted requirements come from the International Air Transport Association (IATA). Most national and international regulations are based on or are at least in substantial agreement (harmonization) with IATA requirements. In the United States, the DOT regulates the commercial transport of dangerous goods by both air and ground carriers. The DOT revised its regulations for the transportation of infectious substances to be in substantial harmonization with IATA requirements. These regulations dictate the packaging and labeling of infectious material that is shipped via commercial carriers with the stated goal of protecting employees in the transportation industry and the general public. This protection is based on packages that are unlikely to leak or be damaged during shipment, labels affixed to the package that identify the particular hazard, and trained personnel who are responsible for the shipment of infectious material. These regulations and guidelines are constantly evolving as the various groups and organizations attempt to agree on one set of standards.

Infectious Substances Classification

Classes of dangerous goods that are regulated include explosives, gases, flammables (liquids and solids), oxidizing substances, toxic and infectious substances, radioactive material, corrosives, and miscellaneous (includes dry ice). The two classes encountered in the clinical laboratory are class 6 (toxic [6.1] and infectious substances [6.2]) and class 9 miscellaneous dangerous goods (including dry ice). Infectious substances are materials known or suspected to contain a pathogen with the potential to cause disease upon exposure. A pathogen is a virus or microorganism (including its plasmids or other genetic elements) or proteinaceous particle (prion) that has the potential to cause disease in humans or animals. In most clinical

本书版权归John Wiley & Sons Inc.所有

laboratories, division 6.2 infectious substances must be classified into one of the following three types:

- Category A infectious substance
- Category B infectious substance
- Exempt human specimen

A category A substance (pathogen or agent) is "an infectious substance which is transported in a form that, when exposure occurs, is capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals." Category A pathogens were previously classified as WHO risk group 4 substances and ostensibly encompass cultured select agent organisms. A nonexhaustive list of category A pathogens is available from the latest IATA Dangerous Goods Regulations (64). If there is doubt as to whether or not a substance meets the criteria of category A, it must be included in category A. Category A pathogens must be assigned the UN number UN2814 (infectious substance, affecting humans) or UN2900 (infectious substance, affecting only animals). Category A pathogens that may affect both humans and animals, such as *Brucella* spp., should be shipped as UN2814. A category B substance is defined by IATA as "an infectious substance which does not meet the criteria for inclusion in Category A." Category B substances are not in a form generally capable of causing disability, life-threatening illness, or fatal disease. Examples include typical clinical, diagnostic, or patient specimens and typical clinical laboratory cultures of routinely encountered non–category A microorganisms. Category B substances must be assigned UN number UN3373 (biological substance, category B). Exempt specimens are those for which there is "minimal likelihood there are pathogens present." A patient specimen is material collected directly from humans for diagnostic, treatment, prevention, investigational, or research purposes. Patient specimens that have category A or B criteria should be classified, packed, and shipped as category A or B. Patient specimens that have neither category A nor B criteria should be packed and shipped as exempt human specimens (Table 25.10). For category A shipments, an itemized list of contents must be placed between the secondary and outer packaging.

The shipper is legally responsible for correctly classifying the material being shipped and for packing substances correctly to ensure the safety of all personnel who handle the package before, during, and even after shipment to the point of acceptance of the package by the consignee. When there is uncertainty about the infectious nature of the material, it is prudent to declare and ship the material as an infectious substance. The following questions may be helpful for classifying diagnostic specimens and biological products (66) and in determining substances that are regulated.

Table 25.10 Shipping classification examples

Substance	Classification	UN number/ label
Blood sample suspected to contain Ebola virus	Category A; infectious substance, affecting humans	UN2814
Culture of foot and mouth disease virus	Category A; infectious substance, affecting animals	UN2900
Blood sample suspected to contain hepatitis B virus	Category B, biological substance	UN3373
Blood sample for cholesterol testing	Exempt	Exempt human specimen

- Is the substance known or suspected to contain a pathogen?
- Is the sample being shipped for diagnostic or investigational purposes?
- Is there a low probability for the occurrence of risk group 4 pathogens in the sample?
- Is the sample known not to contain a pathogen?
- Is the substance a licensed biological product?
- Is the substance being shipped for any other reason?

Packaging, Labeling, and Shipping Regulated Material

All packages containing infectious substances must meet the shipping regulations of various organizations or agencies (44, 64, 67). However, the IATA requirements are usually acceptable under all regulations. They require triple packaging consisting of a primary receptacle that is leakproof, secondary packaging that is also leakproof, and an outer package that is durable (Appendix 25.7). These containers are commercially available. For liquid infectious substances, an absorbent material should be placed between the primary receptacle and secondary packaging and be sufficient to absorb the entire contents.

There are specific instructions for labeling packages containing infectious substances, diagnostic specimens, and biological products (68). Under IATA requirements, labeling and marking of the outer package must include the following as appropriate for the substance (Appendix 25.8):

- An address label with the shipper's and receiver's names and addresses
- A hazard label for category A shipments: "Infectious Substance" label UN2814 or UN2900
- A hazard label for dry ice: class 9 "Miscellaneous Dangerous Goods" label

本书版权归John Wiley & Sons Inc.所有

- Marking required for category B shipments: UN3373
- Label for "Exempt Human Specimens" if neither category A nor B

A shipper's declaration is required for dry ice (a dangerous good) if dry ice is used as a refrigerant for a category A substance, but not for a category B substance or exempt human specimens. A shipper's declaration form may be available electronically from the carrier. The shipper should prepare at least three copies: one for their records and two for the carrier. The carrier must deliver a copy to the consignee. The shipping documents must be affixed to the outer package and include the shipper's declaration (Appendix 25.9) and an airway bill if shipping by air. Orientation labels (arrows) must be placed on all packages containing greater than 50 ml of material.

The Federal Aviation Administration and/or DOT may inspect any shipper or receiver of dangerous goods unannounced at any time. The inspector may review training records, oversee the actual packaging and labeling of a shipment, and/or call the 24-hour emergency number listed on the paperwork. The shipper or receiver may be quizzed on the hazards and characteristics of the dangerous goods, the proper decontamination and disposal of the hazardous material (information found on the MSDS), and accident mitigation. It is critical that the training program for the shipment of dangerous goods emphasizes this safety information. Anyone involved in the shipping or transportation of dangerous goods must be trained and certified. Recertification is required every 2 years for IATA and 3 years for DOT, unless required more frequently by the laboratory's accrediting body (69).

Personnel Training

Safety training and the education of workers about potential hazards and safe work practices are essential to creating a safe work environment (9, 11). All personnel employed in the clinical laboratory must receive adequate safety training applicable to their positions in order to perform their assigned tasks in a safe manner. Safety policies should be applied to work practices. This training is mandated by various governmental regulations and accreditation organizations and is required for new employees and students, individuals assigned new tasks, before the introduction of new hazards or procedures to the work environment, and on an annual basis for all personnel.

Training Program

The size and complexity of a safety training program will vary with the needs of the institution but must cover all applicable safety topics and policies. Some topics include:

- Chemical information regarding job-specific hazards (e.g., exposure to formaldehyde or carcinogens)
- Management of hazardous material and waste
- Blood-borne pathogen information (epidemiology, symptoms, transmission)
- Standard precautions
- Selection, use, and limitations of PPE, safety equipment, and other control procedures
- Postexposure management, accident reporting, and investigation of incidents
- Emergency preparedness, including fire, natural disaster, active shooter, and bioterrorism issues
- Availability of all safety regulations
- Medical surveillance program
- The employee's responsibility to follow all safety policies and inform supervisors of potential safety hazards

The laboratory safety training program should be developed with input from the infection control practitioner, industrial hygienist, and other knowledgeable individuals; highlight the potential risk from infectious agents and hazardous chemicals; and emphasize the reduced risk when work is performed according to the safety guidelines. The contents of the training program should be updated frequently as new safety information becomes available or regulations change.

Methods

The training format can be lectures, hands-on demonstrations, safety workshops, videos, computer programs, or distance learning. However, no matter which method is used, the trainer must be available to immediately respond to the trainee's questions during the session. The trainer must be competent in the area of laboratory safety and knowledgeable about current safety regulations, work practices, safety equipment, and hazards found in the clinical laboratory.

Documentation

The date of training, a summary of the presentation (or contents of the session), and attendance should be documented and placed in the employee's record. Training records should be maintained for 3 years.

Monitoring and Evaluation

The effectiveness of the training program can be evaluated with a test but realistically must be assessed by observing the daily practices of the employees for compliance with safety policies. When safety practices are not followed, the individual should be counseled and reeducated on the appropriate practice. Repeated disregard for safety guidelines should trigger strict disciplinary action. It is the employer's responsibility to enforce adherence to safe work practices.

本书版权归John Wiley & Sons Inc.所有

The overall effectiveness of the laboratory safety program is assessed through safety audits (Table 25.11), inspections by outside agencies and organizations, review of incident and accident reports (Appendix 25.10), and observations and suggestions from employees. Audits and inspections should highlight concerns and provide recommendations to improve the safety program. Management provides the resources to address and correct any deficiencies, beginning with the most frequent and severe problem. However, in the end, a safe workplace develops from the efforts of all individuals in the organization.

Table 25.11 Sample laboratory safety audit

Date: _____ Location: _____

Instructions:

- Answer yes, no, or N/A (not applicable)
- Explain N/A responses on separate sheet
- If insufficient space, include information on separate page

General	**Describe deficiency**
_____ Has a Safety Officer been appointed?	_____
_____ Employee safety training at hire and then annually?	_____
_____ Current posted listing of emergency contacts?	_____
_____ Are BSCs certified annually?	_____
_____ Blood-borne pathogen and chemical spill kits available?	_____
_____ Are chemical fume hoods certified annually?	_____
Housekeeping/signage	
_____ Are aisles/hallways unobstructed?	_____
_____ Are work surfaces routinely disinfected?	_____
_____ Are doors and storage areas labeled appropriately?	_____
_____ Are proper warning labels on containers?	_____
_____ Are handwashing sinks available?	_____
_____ Are heavy objects stored on lower shelving?	_____
_____ Are biohazard receptacles separate from regular trash?	_____
_____ Is trash removed at least once daily or when full?	_____
_____ Is storage in hoods limited to not obstruct ventilation?	_____
_____ Are tops of centrifuges locked down when in use?	_____
_____ Are refrigerators clean and defrosted?	_____
Personal Protective Equipment	
_____ Has PPE assessment been completed and documented?	_____
_____ Are proper lab coats worn while in work area?	_____
_____ Are lab coats and gloves removed before leaving the lab?	_____
_____ Are appropriate gloves worn while testing?	_____
_____ Are gloves available in appropriate sizes?	_____
_____ Are glove liners available for those with latex allergy?	_____
Documentation	
_____ Are current CLSI documents M29 and GP17 available?	_____
_____ Are safety training records kept for three years?	_____
Blood-borne pathogens	
_____ Is blood-borne pathogen written program available?	_____
_____ Do employees understand standard precautions?	_____
_____ Are hands washed before leaving the work area?	_____
_____ Are sharps containers disposed of when ¾ full?	_____
_____ Is mouth pipetting prohibited?	_____
_____ Do employees refrain from eating or drinking in lab?	_____
_____ Are those shipping infectious substances certified?	_____

本书版权归John Wiley & Sons Inc.所有

Table 25.11 *(continued)*

Chemical Hygiene	
_____ Is chemical hygiene plan available and current?	_____
_____ Do employees know where MSDSs are located?	_____
_____ Has the chemical inventory been performed and updated?	_____
_____ Is there a list of carcinogens, mutagens, teratogens?	_____
_____ Has chemical risk assessment been updated?	_____
_____ Are chemicals stored appropriately?	_____
_____ Have employees been trained in spill cleanup?	_____
Fire	
_____ Is there a fire alarm pull station nearby?	_____
_____ Can fire alarm be heard in the lab?	_____
_____ Are emergency exits accessible?	_____
_____ Are fire extinguishers accessible?	_____
_____ Have fire extinguishers been serviced?	_____
_____ Have quarterly fire drills been completed/documented?	_____
Waste Management	
_____ Is there a waste management plan?	_____
_____ Is there a recycling program?	_____
_____ Is waste disposed of according to regulations?	_____
_____ Has the use of mercury been eliminated in the lab?	_____

SUMMARY

The laboratory contains many biological, chemical, radiological, and physical hazards, including new infectious agents and the possibility of the use of biological and chemical agents for acts of terrorism. However, many tools and practices are available to reduce the occupational risk from exposure to these hazards, including safety devices, standard precautions, PPE, BSCs and chemical fume hoods, warning signs and labels, safe work practices, and proper disposal of biological and chemical waste. A well-written safety management plan is a blueprint for implementation of safe practices and includes the necessary training to produce a safe work environment.

KEY POINTS

- Laboratory workers are exposed to biological, chemical, physical, and radiological hazards.
- A well-written and enforced safety management plan can minimize occupational risk.
- All laboratory personnel should adhere to the concept of standard precautions and use available barrier precautions.

GLOSSARY

Aerosol A system of respirable particles dispersed in a gas, smoke, or fog that can be retained in the lungs.

Airborne transmission The spread of infection by inhalation of droplet nuclei containing an infectious agent.

Blood-borne pathogens Pathogenic microorganisms that are present in human blood and can cause disease in humans.

Carcinogen Substance capable of causing a malignant tumor in humans or animals.

Category A substance An infectious substance or microorganism that is transported in a form that, when exposure to it occurs, is capable of causing permanent disability or life-threatening or fatal disease in an otherwise healthy human or animal.

Category B substance An infectious substance that does not meet category A criteria. Category B substances generally are considered to be one of the following: (i) patient or clinical specimen reasonably expected to contain, or being cultured or otherwise tested for, a pathogen and (ii) microorganisms not specifically listed in category A.

Ceiling limit The airborne concentration of a substance that cannot be exceeded at any time during the workday.

Contaminated Describes the presence or reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Corrosive Any substance that causes visible destruction of human tissue at the site of contact. The U.S. Environmental Protection Agency defines corrosivity as a substance that is highly acidic (pH < 2.1) or highly alkaline (pH > 12.4).

Decontamination A procedure that eliminates or reduces microbial or toxic agents to a safe level with respect to the transmission of infection or other adverse effects.

Disinfectant An agent intended to destroy or irreversibly inactivate all microorganisms, but not necessarily their spores, on inanimate surfaces, e.g., work surfaces or medical devices.

本书版权归John Wiley & Sons Inc.所有

Disinfection A procedure that kills pathogenic microorganisms but not necessarily their spores.

Engineering controls Controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices) that isolate or remove the hazard from the workplace.

Germicide A general term for an agent that kills pathogenic microorganisms on inanimate surfaces.

Infectious waste Waste containing or assumed to contain pathogens of sufficient virulence and quantity that exposure to the waste by a susceptible host may result in a communicable disease.

International Air Transport Association (IATA) A trade organization of the commercial airline industry that governs international aviation and publishes *Dangerous Goods Regulations* for use by anyone who packs, ships, or handles dangerous goods.

Latex allergy Allergic reaction associated with latex glove use. The two types of allergic reactions are contact dermatitis (type IV delayed hypersensitivity), due to chemicals used in processing latex, and the more serious immunoglobulin E/histamine-mediated allergy (immediate or type I hypersensitivity), due to latex proteins.

Material safety data sheet (MSDS) Provides detailed information about hazards and protective measures relative to hazardous chemical substances.

Occupational exposure Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with a hazard that may result from the performance of an employee's duties.

Other potentially infectious material (OPIM) Human body fluids including semen, vaginal secretions, urine, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva, body fluids that may be contaminated with blood, unfixed tissue, HIV- or hepatitis virus–containing cell or organ cultures, blood or tissue from an infected animal, reagents, infectious waste, and cultures.

Parenteral Piercing mucous membranes or the skin through events such as needlesticks, human bites, and abrasions.

Permissible exposure limit (PEL) Maximum allowed exposure during a time-weighted average period (e.g., 8-hour workday or 40-hour workweek).

Personal protective equipment (PPE) Specialized clothing or equipment worn by an employee for protection against a hazard.

Primary container A vessel, including its closure, that contains a specimen.

Prions Infectious, abnormal host proteins that cause transmissible spongiform encephalopathies and are resistant to a number of standard disinfection and sterilization procedures.

Regulated waste Liquid or semiliquid blood or OPIMs, contaminated items that would release blood or OPIMs in a liquid or semiliquid state if compressed, items that are caked with dried blood or OPIMs and are capable of releasing these materials during handling, contaminated sharps, and pathological and microbiological wastes containing blood or OPIMs.

Secondary container A vessel into which the primary container is placed for transport within an institution. It contains a specimen if the primary container breaks or leaks in transit.

Sharps container A container approved for the containment and transport of contaminated sharps.

Standard precautions Set of precautions applied to all patients, regardless of disease status; designed to reduce risk of transmission of microorganisms in the healthcare setting; introduced by the CDC by combining universal precautions with body substance isolation, which emphasized the use of PPE and hand hygiene.

Short-term exposure limit Maximum exposure to a hazardous substance allowed at one time (normally measured in a single 15-minute period).

Sterilant An agent intended to destroy all microorganisms (viruses, vegetative bacteria, fungi, and a large number of highly resistant bacterial endospores) on inanimate surfaces.

Sterilization A procedure that effectively kills all microbial life, including bacterial spores, on inanimate surfaces.

Universal precautions Set of precautions designed to reduce the risk of transmission of HIV, HBV, and other blood-borne pathogens in the healthcare setting by treating all blood, body fluid, and other potentially infectious materials (OPIM) as potentially infectious.

REFERENCES

1. **Fleming DO**. 2006. Risk assessment of biological hazards, p 57–64. *In* Fleming DO, Hunt DL (ed), *Biological Safety: Principles and Practices*, 4th ed. ASM Press, Washington, DC.

2. **Songer JR**. 1995. Laboratory safety management and the assessment of risk, p 257–277. *In* Fleming DO, Richardson JH, Tulis JJ, Vesley D (ed), *Laboratory Safety: Principles and Practices*, 2nd ed. ASM Press, Washington, DC.

3. **Phillips GB**. 1986. Human factors in microbiological laboratory accidents, p 43–48. *In* Miller BM, Groeschel DHM, Richardson JH, Vesley D, Songer JR, Housewright RD, Barkley WE (ed), *Laboratory Safety: Principles and Practice*. American Society for Microbiology, Washington, DC.

4. **Richmond JY**, **Nesby-O'Dell SL**, **Centers for Disease Control and Prevention**. 2002. Laboratory security and emergency response guidance for laboratories working with select agents. *MMWR Recomm Rep* **51**(RR-19):1–6.

5. **Gilchrist MJR**, **McKinney WP**, **Miller JM**, **Weissfeld AL**. 2001. Cumitech 33: Laboratory Safety, Management, and Diagnosis of Biological Agents Associated with Bioterrorism. Coordinating ed, Snyder JW. ASM Press, Washington, DC.

6. **Henderson DK**. 2003. Managing occupational risks for hepatitis C transmission in the health care setting. *Clin Microbiol Rev* **16**:546–568.

7. **Henderson DK**, **Dembry L**, **Fishman NO**, **Grady C**, **Lundstrom T**, **Palmore TN**, **Sepkowitz KA**, **Weber DJ**, **Society for Healthcare Epidemiology of America**. 2010. SHEA guideline for management of healthcare workers who are infected with hepatitis B virus, hepatitis C virus, and/or human immunodeficiency virus. *Infect Control Hosp Epidemiol* **31**:203–232.

本书版权归John Wiley & Sons Inc.所有

8. Centers for Disease Control and Prevention and National Institutes of Health (CDC/NIH). 2020. *Biosafety in Microbiological and Biomedical Laboratories*, 6th ed. HHS Publication No. (CDC) 300859 ed. US Government Printing Office, Washington, DC.

9. Clinical and Laboratory Standards Institute. 2014. Protection of laboratory workers from occupationally acquired infections. Approved guideline. 4th ed. Clinical and Laboratory Standards Institute, Wayne, PA.

10. Clinical and Laboratory Standards Institute. 2016. Laboratory design. 3rd ed. CLSI guideline QMS04. Clinical and Laboratory Standards Institute, Wayne, PA.

11. Hoeltge GA. 2002. Laboratory safety, p 78–96. *In* McClatchey KD (ed), *Clinical Laboratory Medicine*, 2nd ed. Lippincott Williams and Wilkins, Philadelphia, PA.

12. McGowan JE Jr. 1999. Nosocomial infections in diagnostic laboratories, p 1127–1135. *In* Mayhall CG (ed), *Hospital Epidemiology and Infection Control*, 2nd ed. Lippincott Williams and Wilkins, Philadelphia, PA.

13. Lagacé-Wiens P, **Pentella M**. 2019. Prevention and control of laboratory-acquired infections, p 206–223. *In* Carroll KC, Pfaller MA, Landry ML, McAdam AJ, Patel R, Richter SS, Warnock DW (ed), *Manual of Clinical Microbiology*, 12th ed. ASM Press, Washington, DC.

14. Clinical and Laboratory Standards Institute. 2012. Clinical laboratory safety. Approved guideline. 3rd ed. CLSI document GP17-A3. Clinical and Laboratory Standards Institute, Wayne, PA.

15. Gilpin RW. 2000. Elements of a biosafety program, p 443–462. *In* Fleming DO, Hunt DL (ed), *Biological Safety: Principles and Practices*, 3rd ed. ASM Press, Washington, DC.

16. Occupational Safety and Health Administration. 1990. *Hazard Communication Standard*. 29 CFR 1910.1200. U.S. Government Printing Office, Washington, DC.

17. Occupational Safety and Health Administration. 1991. Occupational exposure to bloodborne pathogens—OSHA. Final rule. *Fed Regist* **56**:64004–64182.

18. Occupational Safety and Health Administration. 1990. *Occupational Exposure to Hazardous Chemicals in the Laboratory*. 29 CFR 1910.1450. U.S. Government Printing Office, Washington, DC.

19. Harding AL, **Byers KB**. 2006. Epidemiology of laboratory-associated infections, p 35–54. *In* Fleming DO, Hunt DL (ed), *Biological Safety: Principles and Practices*, 4th ed. ASM Press, Washington, DC.

20. Centers for Disease Control and Prevention (CDC). 2002. Laboratory-acquired meningococcal disease—United States, 2000. *MMWR Morb Mortal Wkly Rep* **51**:141–144.

21. Jensen PA, **Lambert LA**, **Iademarco MF**, **Ridzon R**, **CDC**. 2005. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR Recomm Rep* **54**(RR-17):1–141.

22. Beltrami EM, **Williams IT**, **Shapiro CN**, **Chamberland ME**. 2000. Risk and management of blood-borne infections in health care workers. *Clin Microbiol Rev* **13**:385–407.

23. Siegel JD, **Rhinehart E**, **Jackson M**, **Chiarello L**, Health Care Infection Control Practices Advisory Committee. 2007. Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings. *Am J Infect Control* **35**(Suppl 2):S65–S164.

24. Sewell DL. 1995. Laboratory-associated infections and biosafety. *Clin Microbiol Rev* **8**:389–405.

25. Sewell DL. 2006. Laboratory-acquired infections: are microbiologists at risk? *Clin Microbiol Newsl* **28**:1–6.

26. Dingle TC, **Butler-Wu SM**, **Abbott AN**. 2014. Accidental exposure to *Burkholderia pseudomallei* in the laboratory in the era of matrix-assisted laser desorption ionization-time of flight mass spectrometry. *J Clin Microbiol* **52**:3490–3491.

27. Rudrik JT, **Soehnlen MK**, **Perry MJ**, **Sullivan MM**, **Reiter-Kintz W**, **Lee PA**, **Pettit D**, **Tran A**, **Swaney E**. 2017. Safety and accuracy of matrix-assisted laser desorption ionization-time of flight mass spectrometry for identification of highly pathogenic organisms. *J Clin Microbiol* **55**:3513–3529.

28. Cunningham SA, **Patel R**. 2015. Standard matrix-assisted laser desorption ionization-time of flight mass spectrometry reagents may inactivate potentially hazardous bacteria. *J Clin Microbiol* **53**:2788–2789.

29. Burnett LC, **Lunn G**, **Coico R**. 2009. Biosafety: guidelines for working with pathogenic and infectious microorganisms. *Curr Protoc Microbiol*. Ch. 1, unit 1A.1

30. Choy KW. 2020. Changes in clinical laboratory operations and biosafety measures to mitigate biohazard risks during the COVID-19 pandemic. *Lancet Microbe* **1**:e273–e274.

31. Centers for Disease Control and Prevention. Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19). https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html. Accessed 7 December 2021.

32. Occupational Safety and Health Administration. Control and Prevention of COVID-19. https://www.osha.gov/coronavirus/control-prevention. Accessed 7 December 2021.

33. Tweedy JT. 1997. *Healthcare Hazard Control and Safety Management*. Lewis Publishers, Boca Raton, FL.

34. Centers for Disease Control. 1987. *Registry of Toxic Effects of Chemical Substances*. U.S. Government Printing Office, Washington, DC.

35. National Institutes of Health. 1985. *Pocket Guide to Chemical Hazards*. U.S. Government Printing Office, Washington, DC.

36. Mahoney W, **Salkin IF**. 1992. Radiological safety, p 14.3.1–14.3.3. *In* Isenberg HD (ed), *Clinical Microbiology Procedures Handbook*, vol. 2. American Society for Microbiology, Washington, DC.

37. Centers for Disease Control and Prevention. 2023. Support for public health workers and health professionals. https://www.cdc.gov/mentalhealth/public-health-workers/. Accessed 9 October 2023.

38. Canadian Society for Medical Laboratory Science.2016. Describing mental health issues for medical laboratory professionals in the workplace. https://www.csmls.org/csmls/media/documents/resources/Describing-Mental-Health-Issues-for-MLPs-v02.pdf. Accessed 7 December 2021.

39. Centers for Disease Control and Prevention. 2023. Coping with stress. https://www.cdc.gov/mentalhealth/stress-coping/. Accessed 9 October 2023.

40. Hunt DL. 2006. Standard (universal) precautions for human specimens, p 355–367. *In* Fleming DO, Hunt DL (ed), *Biological Safety: Principles and Practices*, 4th ed. ASM Press, Washington, DC.

本书版权归John Wiley & Sons Inc.所有

41. Occupational Safety and Health Administration. 2001. Pathogens (29CFR 1910.1030) directives numbers: CPL 2-2.69; effective: 27 November 2001.

42. U.S. Public Health Service. 2001. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis. *MMWR Recomm Rep* **50**(RR-11):1–52.

43. Knudsen RC. 1998. Risk assessment for biological agents in the laboratory. *In* Richmond JY (ed), *Rational Basis for Biocontainment: Proceedings of the Fifth National Symposium on Biosafety*. American Biological Safety Association, Mundelein, IL.

44. World Health Organization (ed). 2004. *Laboratory Biosafety Manual*, 3rd ed. World Health Organization, Geneva, Switzerland.

45. Gilchrist MJR, Hindler J, Fleming DO. 1992. Laboratory safety management, p xxix–xxxvii. *In* Isenberg HD (ed), *Clinical Microbiology Procedures Handbook*, vol. 2. American Society for Microbiology, Washington, DC.

46. Centers for Disease Control and Prevention and U.S. Department of Agriculture. 2023. Federal Select Agent Program, Select agents and toxins list. https://www.selectagents.gov/sat/list.htm. Accessed 9 October 2023.

47. Favero MS, Arduino MJ. 2000. Decontamination and disinfection, p 383–402. *In* Fleming DO, Hunt DL (ed), *Biological Safety: Principles and Practices*, 3rd ed. ASM Press, Washington, DC.

48. Boyce JM, Pittet D, Healthcare Infection Control Practices Advisory Committee, HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force, Society for Healthcare Epidemiology of America/Association for Professionals in Infection Control/Infectious Diseases Society of America. 2002. Guideline for Hand Hygiene in Health-Care Settings. Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *MMWR Recomm Rep* **51**(RR-16):1–45, quiz CE1–CE4

49. Denys GA. 2010. Biological safety and biohazard prevention, p 15.1.1–15.2.4.3. In Garcia LS (ed), *Clinical Microbiology Procedures Handbook*, 3rd ed. ASM Press, Washington, DC.

50. Clinical and Laboratory Standards Institute. 2002. Implementing a needlestick and sharps injury prevention program in the clinical laboratory; a report. CLSI document X3-R. Clinical and Laboratory Standards Institute, Wayne, PA.

51. Occupational Safety and Health Administration. 2001. Occupational exposure to bloodborne pathogens; needlestick and other sharps injuries; final rule. Occupational Safety and Health Administration (OSHA), Department of Labor. Final rule; request for comment on the Information Collection (Paperwork) Requirements. *Fed Regist* **66**:5317–5325.

52. Pearson ML, Bridges CB, Harper SA, Healthcare Infection Control Practices Advisory Committee (HICPAC), Advisory Committee on Immunization Practices (ACIP). 2006. Influenza vaccination of health-care personnel: recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* **55**(RR-2):1–16.

53. Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention (CDC). 2011. Immunization of health-care personnel: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* **60**(RR-7):1–45.

54. Centers for Disease Control and Prevention and National Institutes of Health (CDC/NIH). 2007. *Primary Containment of Biohazards: Selection, Installation and Use of Biological Safety Cabinets*, 3rd ed. U.S. Government Printing Office, Washington, DC.

55. Aguzzi A, Glatzel M. 2011. Transmissible spongiform encephalopathies, p 1677–1683. *In* Versalovic J, Carroll KC, Funke G, Jorgensen JH, Landry ML, Warnock DW (ed), *Manual of Clinical Microbiology*, 10th ed. ASM Press, Washington, DC.

56. Favero MS, Bond WW. 2001. Chemical disinfection of medical and surgical materials, p 881–917. *In* Block SS (ed), *Disinfection, Sterilization, and Preservation*, 5th ed. Lippincott Williams and Wilkins, Philadelphia, PA.

57. Fleming DO. 2006. Prudent biosafety practices, p 369–381. *In* Fleming DO, Hunt DL (ed), *Biological Safety: Principles and Practices*, 4th ed. ASM Press, Washington, DC.

58. Clinical and Laboratory Standards Institute. 2011. Clinical laboratory waste management. Approved guideline. 3rd ed. Clinical and Laboratory Standards Institute, Wayne, PA.

59. Keene JH. 2000. Regulated medical waste handling and disposal, p 403–409. *In* Fleming DO, Hunt DL (ed), *Biological Safety: Principles and Practices*, 3rd ed. ASM Press, Washington, DC.

60. U.S. Department of Transportation. 1991. Performance-orientated packaging standards: revisions and response petitions for reconsideration. *Fed Regist* **56**:66124–66287.

61. U.S. Department of Transportation. 1996. *49 CFR Parts 171–180. Hazardous Materials Regulations: Public Health Service 42 CFR Part 72. Interstate Transportation of Etiologic Agents*. U.S. Government Printing Office, Washington, DC.

62. The Joint Commission. 2021. *Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing*. Joint Commission Resources, Oakbrook Terrace, IL.

63. Denys GA, Relich RF. 2016. Management of infectious waste, p 15.8.1–15.8.6. *In* Leber AL (ed), *Clinical Microbiology Procedures Handbook*, 4th ed. ASM Press, Washington, DC.

64. International Air Transport Association (IATA). 2021. *Dangerous Goods Regulations*, 62nd ed. International Air Transport Association, Montreal, Quebec.

65. U.S. Department of Transportation. 1996. *49 CFR 173.134(a)(4). Regulated Medical Waste*. U.S. Government Printing Office, Washington, DC.

66. Snyder JW. 2002. Packaging and shipping of infectious substances. *Clin Microbiol Newsl* **24**:89–93.

67. U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration. 2006. Hazardous materials: infectious substances; harmonization with the United Nations recommendations; final rule. *Fed Regist* **71**:32244–32263.

68. Gray LD, Snyder JW. 2006. Packaging and shipping biological materials, p 411–425. *In* Fleming DO, Hunt DL (ed), *Biological Safety: Principles and Practices*, 4th ed. ASM Press, Washington, DC.

69. Gray LD. 2016. Packing and shipping infectious substances, p 15.6.1–15.6.24. *In* Leber AL (ed), *Clinical Microbiology Procedures Handbook*, 4th ed. ASM Press, Washington, DC.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 25.1 Sample Form for Declination of Hepatitis B Vaccination[a]

[a] See reference 41.

HEPATITIS B VACCINE DECLINATION

I understand that due to my occupational exposure to blood, or other potentially infectious materials, I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with HBV vaccine, at no charge to myself. However, I decline HBV vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If, in the future, I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with HBV vaccine, I can receive the vaccination series at no charge to me.

_____ _____

Print full name Date of birth

_____ _____

Signature of employee Date

APPENDIX 25.2 Important Information Resources[a]

U.S. GOVERNMENT AGENCIES

Centers for Disease Control and Prevention (CDC)
http://www.cdc.gov
Resources related to public health issues in the United States.

U.S. Department of Health and Human Services (HHS)
http://www.hhs.gov
Information on policies and regulations, disasters and emergencies, safety, diseases and conditions, aging, resource locators, drugs and food, and other topics.

U.S. Department of Transportation (DOT)
http://www.transportation.gov
Resources related to the transportation of infectious and diagnostic specimens.

U.S. Environmental Protection Agency (EPA)
http://www.epa.gov
Information on general-purpose disinfectants.

U.S. Food and Drug Administration (FDA)
http://www.fda.gov
Information on chemical germicides formulated as antiseptics, preservatives, sterilants, high-level disinfectants, and agents used on the body.

National Institute for Occupational Safety and Health (NIOSH)
http://www.cdc.gov/niosh
Training materials and information on chemical agents and emergency preparedness.

Occupational Safety and Health Administration (OSHA)
http://www.osha.gov
Training materials, standards, and regulations related to safety in the workplace.

Safe Labs
http://www.cdc.gov/safelabs
Training materials and information on safety, biosafety, and safety survival skills.

U.S. Government Publishing Office
http://www.gpo.gov/fdsys
A source for federal regulations.

BIOSAFETY RESOURCES

CDC/NIH: Biosafety in Microbiological and Biomedical Laboratories, 6th ed.
https://www.cdc.gov/labs/BMBL.html
Information on biological risk assessment, laboratory biosafety level criteria, biosecurity, primary containment for biohazards, decontamination and disinfection, and transportation of infectious substances.

Medical Surveillance and Biosafety Program References
http://www.cdc.gov/safelabs
References on occupational health and laboratory safety with materials on medical screening and surveillance.

International Healthcare Worker Safety Center
http://www.internationalsafetycenter.org
Information on the prevention of occupational transmission of blood-borne pathogens and resources for complying with the federal Needlestick Safety and Prevention Act.

(continued)

本书版权归John Wiley & Sons Inc.所有

APPENDIX 25.2 Important Information Resources[a] *(continued)*

BIOTERRORISM

American Society for Microbiology (ASM)
http://www.asm.org
Information related to bioterrorism and protocols for the isolation and identification of select agents.

Bioterrorism Preparedness and Response
http://www.emergency.cdc.gov/bioterrorism
Information on bioterrorism preparedness, training materials, and protocols for handling, identifying, and shipping select agents.

Health Alert Network
http://www.emergency.cdc.gov/HAN
Communications to local and state health departments, distance learning offerings from the CDC, and health alerts.

Infectious Diseases Society of America (IDSA)
http://www.idsociety.org
Clinical information related to bioterrorism and select agents.

SHIPPING AND PACKAGING OF INFECTIOUS SUBSTANCES

International Air Transport Association (IATA)
http://www.iata.org
Information on shipping dangerous goods.

GUIDELINES, STANDARDS, AND ACCREDITATION

Clinical Laboratory Standards Institute (CLSI)
http://www.clsi.org
Information on laboratory standards and guidelines.

College of American Pathologists (CAP)
http://www.cap.org
Standards for laboratory accreditation.

The Joint Commission
http://www.jointcommission.org
Information on standards for accreditation.

[a] Last accessed 7 December 2021.

APPENDIX 25.3 Common Safety Compliance Failures

STANDARD PRECAUTIONS, PPE, AND CONTAINMENT EQUIPMENT

Laboratory coats worn open
Staff not wearing gloves at the workbenches
Handling contaminated objects with gloves (e.g., telephones)
Wearing laboratory coats outside the work area
Not using splash guards or appropriate eyewear when required
Improper storage of chemicals in fume hoods and BSCs
Improper storage of flammables, corrosives, and acids
Overfilled sharps containers
Sharps containers not properly secured
Gas tanks not properly secured
Eyewash stations not checked on a periodic basis
Disposal of biohazardous waste in routine trash receptacles
Food stored in refrigerators containing laboratory supplies

LABELING AND SIGNAGE

Improper labeling of chemical waste containers
Primary and secondary containers not labeled as to hazard
Lack of signage for biohazardous areas

FIRE

Storage of combustibles within 18 inches of sprinkler heads
Hallways used for storage
Fire doors blocked open

CHEMICAL HYGIENE PLAN

Chemical inventories not current
Employees' exposure to OSHA-regulated substances (e.g., formaldehyde) not monitored

TRAINING/MONITORING

Staff lacks knowledge of MSDS location
Staff lacks knowledge of fire alarm and extinguisher location
Accident/incident reports are not submitted or reviewed

本书版权归John Wiley & Sons Inc.所有

APPENDIX 25.4 Biohazard Spill Kit Sample

Disinfectant (e.g., 10% household bleach or a tuberculocidal agent)

Absorbent material
- Small spills: paper towels, gauze pads, etc.
- Large spills: granular material (e.g., BioZorb)

PPE
- Puncture-resistant utility gloves
- Water-impermeable shoe coverings
- Gown
- Eyewear (face shield or goggles)
- Mask
- Full-face respirator or HEPA-filtered mask for BSL-3 agents

Collection material (autoclavable)
- Dustpan
- Tongs or forceps
- Plastic scoop and "pusher"
- Biohazard bag

Puncture-resistant biohazardous waste container

APPENDIX 25.5 Biological Spill Cleanup Procedure (possible aerosol)

Alert personnel in area and evacuate.
Close doors and do not reenter area for 30 to 60 minutes.
Don PPE appropriate for type of spill.
Wear gown, gloves, and facial protection (full-face respirator or HEPA-filtered mask for BSL-3 agents).
Remove and discard broken glass or other objects.
Absorb the spill with absorbent material.
Discard contaminated material in the biohazardous waste container.
Clean the spill site with aqueous detergent.
Decontaminate the area with an appropriate disinfectant.
Pour disinfectant on the spill site or wipe down the site with disinfectant-soaked paper towels or gauze pads.
Absorb the disinfectant or permit it to air dry.
Rinse the spill site with water and allow the site to dry.
Place all disposable, contaminated material in the biohazard bag or container. Treat as infectious waste.
Wash hands.
Prepare a spill/incident report, identify the cause of the spill, and determine remedial action.

APPENDIX 25.6 Minor Chemical Spill Cleanup Procedure[a]

Evacuate personnel in the immediate spill area.
Attend to any contaminated individuals.
Extinguish all sources of ignition.
Contain the spill.
Ventilate the area of the spill.
Close off the spill area (call emergency response team when no trained individuals are available).
Notify safety officials.
Review MSDS for appropriate PPE and specific instructions for cleanup and disposal.
Don appropriate PPE (chemical-resistant gloves, gown, and shoe covers; face shield or goggles; mask).
Dike area of spill to prevent further spread of chemical.
Clean the spill area with appropriate neutralizing agent and absorbent.
Place contaminated material in disposal container.
Scrub area with soap and water.
Package all waste appropriately for pickup. Label containers with substance, amount, and date.
Prepare a spill/incident report, identify cause of spill, and determine remedial action.

[a] Spill does not involve flammables, explosives, carcinogens, or life-threatening chemicals.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 25.7 Shipping Containers[a]

Example of a Category A Shipment

Figure A7.1 Example of packing and marking for category A infectious substances. The smallest external dimension of the outer packaging must not be less than 100 mm; the primary receptacle or secondary receptacle must be capable of withstanding, without leakage, an internal pressure of not less than 95 kPa.

Example of a Category B Shipment

Figure A7.2 Example of packing and marking for category B infectious substances. At least one surface of the outer packaging must have a minimum dimension of 100 mm × 100 mm; the primary receptacle or secondary receptacle must be capable of withstanding, without leakage, an internal pressure of not less than 95 kPa.

本书版权归John Wiley & Sons Inc.所有

Figure A7.3 Example of packing and marking for exempt specimens. At least one surface of the outer packaging must have a minimum dimension of 100 mm × 100 mm; the outer packaging must be of adequate strength for its capacity, mass, and intended use.

[a] Images courtesy of Saf-T-Pak, Inc.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 25.8 Shipping Label Examples[a]

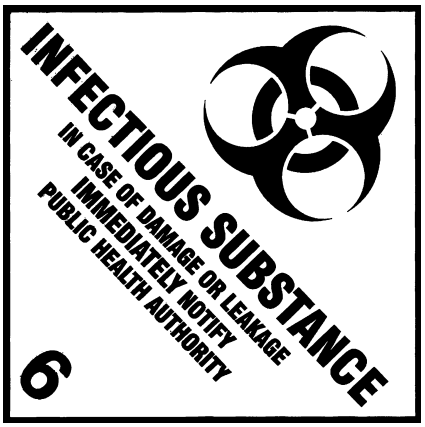


Figure A8.1 Label: infectious substance, category A (class 6).

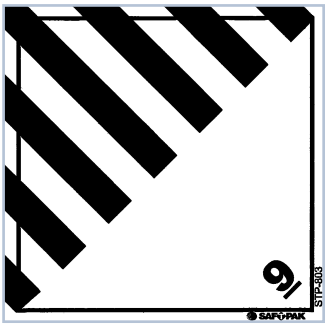


Figure A8.3 Labels: miscellaneous dangerous goods (class 9).

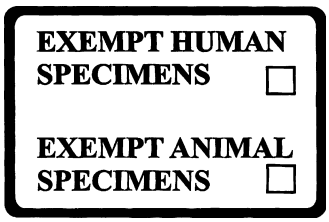


Figure A8.5 Label: exempt human specimen.

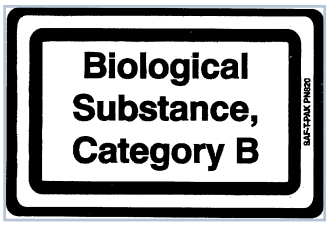


Figure A8.2 Label: biological substance, category B.

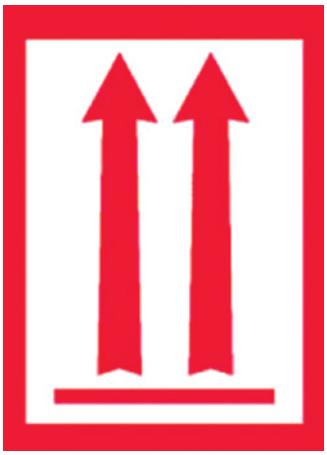


Figure A8.4 Label: package orientation.

[a] Images courtesy of Saf-T-Pak, Inc.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 25.9 Shipper's Declaration for Category A, Infectious Substances

Note: The original shipper's declaration given to the carrier must have vertical red stripes along the left and right edges of the document, and shippers must retain copies for 2 years.

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper
Dr. William Truitt
1234 Blind Lemmon Ave.
Charlotte North Carolina 27105
United States of America

Air Waybill No. _____

Page 1 of 1 Pages

Shipper's Reference Number *(optional)* _____

Consignee
Acme Laboratory
987 Mt. Vernon Ave.
Cincinnati Ohio 45773
United States of America

SAFTPAK™
A Cantel Medical Company

Three completed and signed copies of this Declaration must be produced. One is retained by the shipper and two handed to the operator.

TRANSPORT DETAILS

The packages in this shipment are within the quantity limitations prescribed for: *(strike-out non-applicable)*

~~PASSENGER AND CARGO AIRCRAFT~~	CARGO AIRCRAFT ONLY

Airport of Departure: Charlotte

Airport of Destination: Cincinnati

WARNING

Only trained and certified shippers can sign this form. Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

Shipment type: *(strike-out non-applicable)*

NON-RADIOACTIVE	~~RADIOACTIVE~~

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification				Quantity and type of Packing	Packing Inst.	Authorization
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary risk)	Packing Group			
UN2814	Infectious substance, affecting humans (Brucella spp.)	6.2		1 g	620	
UN1845	Dry ice	9		3 kg All packed in one Fibreboard box	954	

Additional Handling Information

Name and Telephone Number of a Person Responsible: Wm. Truitt 432-321-4567

24-Hour Emergency Contact: 800-123-4567

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.

Name/Title of Signatory
William Doe,
Supervisor

Place and Date
Charlotte, N.C. 28-Sep-2012

Signature
(see warning)

本书版权归John Wiley & Sons Inc.所有

APPENDIX 25.10 Employee Accident and Exposure Report

Employee information (to be completed by the employee)

Name: _____ Employee I.D. number: _____

Date of birth: _____ Sex: M F Home phone: _____ Work phone: _____

Address (include city, state, and ZIP code) _____

Job title: _____ Department: _____

Signature: _____ Date signed: _____

Accident/incident information (to be completed by the employee)

Date incident occurred: _____ Time: _____ Location: _____

Date incident reported: _____ Reported to: _____

List names of witnesses:

Witness statement:

Description and cause of incident (identify injury and part of body):

Blood/body fluid exposure (identify source patient): _____

Supervisor's report

Name: _____ Work phone: _____

Was employee injured during performance of duty? Yes _____ No _____ (explain)

Date medical care received: _____

Do medical reports indicate employee is disabled for work? Yes _____ No _____

Identify corrective actions or safety violations:

Additional comments:

Signature: _____ Date: _____

本书版权归John Wiley & Sons Inc.所有

26

Introduction

Emergency Management Plan
Purpose or Policy • Hazard Analysis • Incident Management System

Elements of an EMP
Emergency Operations Center • Communications • Medical Treatment Areas • Decision to Shut Down Laboratory • Damage Assessment • Evacuation • Personnel Pool • Personnel Care • Locator System • Security • Training • Monitoring and Evaluation

Disasters
Fire • Hazardous Materials • Radioactive Material • Utility Failure • Bomb Threat • Active Shooter/Hostage Response • Natural Disasters • Pandemics • Terrorism Threats • Civil Disorder

SUMMARY
KEY POINTS
GLOSSARY
REFERENCES
APPENDIXES

Emergency Management

Andrea J. Linscott and Natalie Williams-Bouyer

OBJECTIVES

To list emergencies and disasters that could affect the clinical laboratory
To identify the elements of an emergency management plan
To implement the emergency management plan
To evaluate the plan for regulatory compliance

It's no use saying, "We're doing our best." You have got to succeed in doing what is necessary.

Sir Winston Churchill

"Disaster" is defined in the dictionary as a calamitous event, especially one occurring suddenly and causing great loss of life, damage, or hardship, such as a flood, airplane crash, or business failure, whereas "emergency" is defined as an unexpected situation or sudden occurrence of a serious and urgent nature that demands immediate action (1). In the healthcare arena, external emergencies and disasters generally include meteorological disasters (e.g., tornadoes, hurricanes, hailstorms, snowstorms), landslides, floods, earthquakes, tsunamis, warfare, civil disorder, terrorism, and transportation accidents. Due to events surrounding the SARS-CoV-2 (severe acute respiratory syndrome coronavirus type 2) pandemic, we can now add supply chain disruptions to emergency management. Internal emergencies usually include utility failures, hazard spills, fires, bomb threats, and personnel or reagent shortages. A disaster caused by any of these events could ultimately prevent the laboratory from providing test results or services.

Programs or plans that respond to these situations are known as emergency preparedness, emergency management, or disaster plans. In this chapter we will use the term "emergency management plan" (EMP). Often the EMP developed by the laboratory is part of a larger plan for the entire healthcare organization and may be part of a regional or national EMP.

Emergency planning and preparedness are the keys to preventing interruption or cessation of laboratory services when an emergency, disaster, or pandemic occurs. Understanding the type of external and internal disasters or emergencies fosters appropriate preparation and planning that diminishes or eliminates the disruption of services provided by the laboratory and healthcare facility. The EMP collects in one document the information required by employees to respond appropriately to any emergency. Because disasters or emergencies are unpredictable, an EMP can serve only as a guide. The plan

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch26.

本书版权归John Wiley & Sons Inc.所有

assumes that individuals will use good judgment and adapt the response plan to the unique needs of the situation. A well-written EMP can reduce confusion and panic during an emergency, allow responsible individuals to assess the situation and make information-based decisions, and provide a predictable response for the employees (2).

Emergency Management Plan

An organized emergency management program begins with a written comprehensive document that defines the scope and goals of the program and lists the responsible individuals. The College of American Pathologists and The Joint Commission require that laboratories and healthcare facilities have an emergency plan in place and be prepared to accommodate and respond to a disaster so that patient care can be provided in an emergency (3, 4). Accreditation guidelines require that the EMP (i) addresses both internal and external disasters in a general manner such that the facility can respond to multiple scenarios and (ii) documents incidents and training of staff.

The basic EMP should include the following sections.

Purpose or Policy

The purpose or policy states the need for a response plan that deals with the natural or human-caused events that may disrupt normal operations, as well as the responsibility to provide services to patients through effective utilization of limited resources and to assist any injured individuals.

Hazard Analysis

Hazard analysis requires that laboratory personnel prepare a risk assessment for the occurrence of both internal and external disasters, utility failures, hazard spills, epidemics, reagent shortages, civil disorder, and terrorism. This assessment should attempt to define the direct and indirect impact on the facility and reduce the risk or diminish the damage from an emergency or disaster.

Incident Management System

The incident management system is used to manage emergency and disaster events through a flexible response regardless of when or where the event occurs. The first employee to discover the problem is in charge of the emergency response until someone higher in the supervision chain arrives. Each employee is expected to provide the leadership necessary to protect life and property and to carry out the responsibilities of the laboratory. He or she will ensure patient, visitor, and employee safety; will report the incident to the proper authorities; and will use proper procedures as outlined in the plan.

Emergency management generally falls into four phases: (i) identification of the emergency (e.g., tornado, transportation accident, electrical failure, etc.), (ii) containment (limit the impact of the disaster), (iii) response (assist victims and confine the physical damage of the event), and (iv) recovery (restore the organization's normal operation). The plan must reflect and include the facility, local, regional, state, and federal requirements for disaster planning. The laboratory EMP should be complete but concise. To be effective, a plan must be well written and easy to execute. Laboratory staff should be familiar with the plan, the location of the plan, and each individual's role in the execution of the plan. Possible disaster scenarios should be covered in the plan based on the probability or frequency of occurrence of an event for a specific laboratory or geographical location or based on the hazardous material and equipment present in the facility. All plans must consider first the safety of employees, patients, visitors, and individuals with special needs and then address alternative sources of utilities and communications, areas for radioactive or chemical isolation and decontamination, and alternative roles and responsibilities of personnel during the emergency.

For example, the plan must address the following questions in emergency planning and recovery.

Is there sufficient instrumentation to perform testing?

All instruments (or critical instruments) should be on emergency power.

Is an alternative test method or instrumentation available in-house?

Identify manual test methods not requiring instrumentation or use point-of-care test analyzers when laboratory instruments are not available. A standard operation procedure variance may be needed.

Are there sufficient supplies and reagents to perform testing?

As supply chains are often affected, inventory levels may need to be adjusted if there is ample warning. If there is no warning, inventory levels will need to be assessed to determine how long reagents will last if supplies cannot be delivered. A list of alternative resources (vendors or a neighboring laboratory) of supplies and reagents should be available. Phone numbers, both cell and office numbers, fax numbers, and email addresses should be available for any vendor or laboratory that may be called upon.

Are there sufficient personnel to perform testing?

To ensure that sufficient personnel are available, an emergency call-back list should be available at all times. A plan should address possible delays or absence of personnel during a disaster. A plan should address personnel transportation or lodging for a weather-related event.

Is the test menu sufficient to provide requested services?

A test menu may need to be scaled back or specimens sent to a reference laboratory during an emergency.

本书版权归John Wiley & Sons Inc.所有

A plan should include the use of a reference laboratory or discontinuation of certain tests during an emergency.

How will specimens be transported to the laboratory if an electrical or mechanical failure prevents the use of the pneumatic tube system?

A backup plan detailing who will be responsible for getting specimens to the laboratory in the event of pneumatic tube failure should be available.

How will specimens be transported when courier services are not available to deliver specimens from off-site locations?

A plan should include determination of specimen stability if held off-site, alternate travel routes, and/or using alternate laboratory to perform testing for samples that cannot be shipped to your location.

Who will be responsible for the packaging and shipping of specimens or organisms to a reference laboratory?

All federal and state regulations must be followed when specimens are packaged and shipped to another laboratory. A plan outlining who can package and ship specimens or organisms should be available.

The impact of the emergency or disaster on the staff itself must be considered. Ignoring the emotional response to disasters can create a disaster itself, resulting in staff members who are unable to perform the actions required. At a minimum, employee assistance personnel should be contacted to assist when national or local emergencies or disasters directly affect laboratory staff. Immediate and complete verification of personnel location is important when the staff are involved in the emergency. Open, complete communication with status updates is critical to maintaining laboratory operations throughout the disaster. To handle a disaster successfully, the laboratory must anticipate and plan for the problems that will arise. The keys to success include the following elements: (i) development of flow charts detailing potential events and actions to be taken; (ii) identification of the level of laboratory service required based on the anticipated duration and severity of the emergency or disaster; (iii) projection of the impact of limited service on other hospital services, e.g., emergency room, intensive care units; (iv) establishment of effective lines of communication with laboratory staff and other healthcare providers; (v) identification of alternative sites to provide the necessary laboratory services; (vi) plans for recovery activities, e.g., scheduling and staff changes, alternative test procedures, reverification of assays, and (vii) drills to test the effectiveness of the plan. Successful planning must involve all of the affected personnel so that they are aware of their individual responsibilities during an emergency as well as activities necessary to maintain essential services to support patient care activities (Table 26.1).

Table 26.1 Elements of emergency planning

Element	Action
Identify potential disasters and laboratory's response	Prepare list of authorities to notify Identify critical positions and assign individuals Identify critical space and supplies Prepare security measures Develop criteria for evacuation
Define level of service and impact on patient care	Full service (normal operations) Limited service (prioritize testing) Emergency service (prepare minimal test menu) Shut down of laboratory services
Develop communication plan	Identify critical healthcare staff Identify critical laboratory staff (call-back) with all contact information Identify critical suppliers with all contact information
Alternative operations	Identify alternative site of operations Identify alternative laboratory for service work Prepare alternative scheduling or staffing
Drills	Assess performance of emergency plan Modify plan to correct deficiencies

The level of service provided by the laboratory dictates the depth and breadth of involvement by the laboratory staff in disaster recovery. A full-service, hospital-affiliated laboratory may be required to play a more comprehensive role in disaster recovery than a satellite facility or rural laboratory. It is important to recognize, however, that national disasters can significantly affect laboratory operations, regardless of the geographic proximity or services offered. Governmental and private agencies that are available to assist in a large community or regional disaster should be listed in the EMP with contact information (Appendix 26.1).

A business failure, such as manufacturer's recall of products, could also prevent the laboratory from providing services. Just-in-time inventory levels absolutely require a dependable delivery system. The receipt of back-up reagents from other sources depends on the availability of transportation and possible reciprocal relationships with local or regional clinical or reference laboratories. Other possible scenarios that may affect the laboratory, and the questions they raise, include:

- A mail or airline strike or pandemic prevents delivery of reagents or supplies. What is the back-up plan for routine and emergency testing? How quickly can medical staff be notified of a reduction in services based on supply delivery?
- An influx of victims of bioterrorism requires more sophisticated testing than the laboratory has available.

本书版权归John Wiley & Sons Inc.所有

Where should the tests be sent? Who should be notified?

- Staffing levels are routinely at or below minimum levels and an earthquake occurs. How and when does the laboratory manager contact additional staff? What testing should be performed until additional staff arrive?

Emergency planning and preparedness allow for more efficient and effective deployment of activities to mitigate the impact of the disaster on laboratory services and staff. The laboratory manager may assign members of the laboratory staff to assist the facility in maintaining patient services. Emergency management requires that all possible events are considered to ensure that appropriate actions are taken to provide laboratory services where needed and to prevent a negative impact on laboratory operations. To do so, emergencies and disasters are categorized as external or internal to the laboratory and by the severity of the event (Table 26.2). External events occur outside of the physical laboratory and can affect the laboratory's delivery of services or require additional services from the laboratory. Internal emergencies occur within the facility or laboratory and significantly influence delivery of services.

Each laboratory, regardless of size or affiliation with hospitals or clinics, may be required to participate in emergency or disaster recovery in response to national or regional events that include terrorist acts, acts of war, or accidents threatening public safety.

Elements of an EMP

Emergency Operations Center

The emergency operations center (EOC) represents the situational leadership that is necessary to manage the emergency, protect life and property, carry out the function of the laboratory, and assist in other areas of the facility. Generally, individual employees are empowered to manage the event until relieved by someone higher in authority as defined by the order of succession of management. This concept means that individuals must step up and accept responsibility to perform tasks and supervise areas outside of their normal duties. The EMP (Table 26.3) defines who will automatically return to the facility (e.g., department chairperson, laboratory manager), describes the emergency call list, and defines the level of service that will be provided and how personnel will be deployed. Appendixes 26.2 and 26.3 show examples of an EOC checklist and a status report.

Communications

Communication is the most critical and difficult aspect of managing an emergency. The EMP must define the communication lines and how employees will be notified of the emergency. Communication by telephone, cell phones, runners, two-way radios, text alerts, overhead speaker system, and/or other means provides links to internal and external events, responses to the event, and the recovery operation.

Table 26.2 External and internal disasters and impact on the laboratory

Disaster	Impact
External	
Severe weather and natural disasters	Staff availability; relocation of patients and services; utilities and supplies/reagents disrupted
Hazardous material spill or contamination	Staff availability; laboratory services required to treat patients; implement decontamination protocols
Community illness	Staff availability; increase in patient and test volume
Transportation accident	Staff availability; increase in patient volume and specialty requirements (i.e., transfusion services)
National disaster	Supply/reagent availability
National recall of product	Supply/reagent availability
Terrorism	Staff availability; necessary laboratory services for patient care; implement decontamination protocols; increased safety precautions; notification of authorities
Internal	
Utility failure	Services interrupted; relocation or assistance from another laboratory
Hazardous material spill, fire, bomb threat	Personnel affected; testing delayed; special testing may be required; relocation or assistance from another facility
Shortage of personnel	Testing delayed or canceled; assistance from another laboratory
Shortage of reagents or supplies	Testing delayed or canceled; assistance from another laboratory
Civil disorder	Staff availability: supplies/reagents and utilities may be disrupted
Computer issues (security breach, downtime, data loss)	Delay or manual test reporting; incomplete database

本书版权归John Wiley & Sons Inc.所有

Table 26.3 Elements of a laboratory emergency management plan (EMP)

Element	Function
Emergency operation center	Describes leadership hierarchy Constructs emergency call-back list Defines level of service required Deploys laboratory personnel Maintains supply level Establishes communication services
Communication	Defines communication lines Identifies individuals for notification Maintains list of emergency numbers Disseminates information to employees and authorities
Medical treatment areas	Locates medical treatment areas Provides service to the medical treatment areas
Damage assessment	Conducts a damage assessment of laboratory structure, equipment, and reagents Reports assessment to facility's command center Determines need to evacuate
Evacuation	Posts evacuation routes Identifies evacuation leaders Notifies facility's command center
Personnel pool	Assesses availability of personnel Assigns personnel to laboratory or where needed
Locator system	Develops system for tracking location of employees, patients, and visitors Communicates locations to facility's command center
Security	Assigns individual to provide laboratory security until relieved by security personnel Restricts access to laboratory
Training	Addresses personnel responsibility, role in an emergency, communication system, and supply system Conducts drills
Monitoring and evaluation	Documents deficiencies during drills Corrects deficiencies

The EMP should identify who is notified of internal and external disasters (e.g., on-duty staff, off-duty staff, organizational staff, etc.) and should include a list of emergency phone numbers for external agencies and organizations (e.g., local law enforcement agencies, local and regional emergency management organizations, the Federal Bureau of Investigation [FBI], the state health laboratory, the Centers for Disease Control and Prevention [CDC]) that can assist the facility or that may need to be contacted during the emergency (Appendix 26.1). The plan should identify key personnel, their alternates, and their responsibilities. A part of communications involves assessing the nature of the emergency and the potential impact on patients, employees, and the public and developing a plan to include employee meetings, internal dissemination of information, and public information releases. Cell phone texting, cell phone calls, pagers, or internal and external emails can be used to disseminate information depending on the disaster and resources available. It is also important to note that information may change rapidly, and clear concise instructions need to be updated and disseminated, for example, the ever-changing instructions of acceptable collection devices for COVID-19 testing or test code changes due to additional testing platforms being used. Inquiries from outside sources (e.g., press, employee family members) should be forwarded to the individual responsible for addressing these concerns. A hot-line phone system with updated recorded messages can be used to disseminate information to those not on site. Accurate information must be provided to prevent rumors and to inform individuals involved in the event.

Medical Treatment Areas

The laboratory staff must be aware of the areas in the facility that are designated as medical treatment areas, in the event that they require treatment or specimens need to be transported to the laboratory.

Decision to Shut Down Laboratory

A decision may be made to shut a laboratory down when there is ample warning, as in the case of a hurricane, or a laboratory may be shut down due to an emergency. A procedure should be available for how to power down or shut off all instruments, equipment, and computers according to manufacturer's specifications, when possible. In addition, a procedure for steps that need to be taken to bring a laboratory back up should also be included in the EMP. For example, before an instrument or piece of equipment

本书版权归John Wiley & Sons Inc.所有

can be placed back into use, a safety assessment must be performed. Validation of instruments may be warranted, depending on the extent of the damage and time frame in which the instrument was not in use. Storage temperatures should be monitored to ensure that any reagents, collection devices, or equipment are stored within their specified temperature ranges. If temperature ranges are not met and additional product is not readily available, quality control or verification studies may be needed as proof that the product is working as expected.

Damage Assessment

A damage assessment should be performed as soon as possible following a disaster. The assessment can be rapid (5 to 10 minutes) or more detailed (1 to 2 hours) and should determine whether an area can be used safely or must be evacuated (2). The plan must identify who will assess structural damage, equipment failures, hazard contamination, etc. The assessment should provide uniformity in assessing damage due to structural problems and fire and should address safety and the status of the environment (e.g., gas, water, electrical power, lighting, etc.). Damage assessment should also include reviewing temperature charts to determine if reagents were affected by electrical outages. Results are reported to the organization's command center. Assessment of major electrical or structural damage is typically performed by non-laboratory personnel such as facilities, structural engineers, and/or hospital safety officers. These individuals will determine if the area and equipment are safe for working.

Evacuation

Evacuation may be necessary if a fire, hazardous spill, or structural damage occurs. The immediate area should be evacuated, the affected area should be isolated, and the command center should be notified. Evacuation routes must be posted and can be in a vertical or horizontal fashion. Individuals should be identified who are responsible for the safe evacuation of other employees, visitors, patients, and anyone who requires assistance. Employees should not return until authorized by a designated individual.

Personnel Pool

The incident manager (e.g., laboratory manager) will decide which personnel can be released from their normal responsibilities to assist elsewhere in the laboratory or facility. The recent SARS-CoV-2 pandemic has illustrated the need to quickly redeploy laboratory staffing. This pandemic drastically changed the laboratory workflow as outpatient work became almost nonexistent and the bulk of the work was refocused onto the validation and performance of SARS-CoV-2 testing, often on multiple testing platforms. In responding to a pandemic, Clinical Laboratory Scientists (CLSs) from one specialized laboratory department may need to become cross-trained and competent to work in an area where the bulk of the reprioritized lab work must be performed. Cross-training of laboratory personnel can also ensure that individuals are able to work across multiple areas of the lab where operations can continue to run when unforeseen absences or sick leaves arise. For example, several of our CLS personnel working in special chemistry were trained to perform SARS-CoV-2 testing in our molecular laboratory, which was essential to our institutional pandemic response. When employee resources are not in-house, it may be advantageous to hire clinical laboratory personnel through an agency. However, the downfall of utilizing agency CLS staff is the cost, short timeframe to get temporary employees trained and functional, and the short period of time of their contract. However, the advantages of hiring agency staff are that these employees are most often licensed to work in states requiring licensure, and therefore these individuals can be hired quickly.

Personnel Care

Plans for the care of personnel should address the beginning, during, and aftermath of an emergency. Plans should include the availability of staffing and the use of supplemental staff, if needed. It is important to remember that state and federal laws be followed when using supplemental staffing. In areas where known disasters occur, stockpiles of essential items should be available and checked regularly for expiration dates. Stockpile items would include flashlights and batteries, ready-to-eat meals and water, and protective wear like hard hats, etc. For natural disasters that provide some warning (hurricanes, ice storms, etc.), personnel should bring enough personal supplies to last 3 to 5 days. Personal items would include medication, sleeping gear, toiletries, cell phones and chargers, glasses and contact lens items, and snacks. Depending on the emergency, makeshift housing may need to be arranged; often the offices of pathologists or other clinic staff are available for use. Arrangements for family members and pets may also need to be addressed. More frequent breaks may be needed during these times. Downtime activities (card games, watching streaming videos, etc.) may be needed to release stress. Plans should be put into place to protect the personnel from any hazards and to protect personnel when leaving the premises.

Locator System

The EMP must address the problem of communicating the location and status of employees, patients, and visitors to a central location so that the public can locate family and friends quickly. Often victims of a disaster may be spread over an entire metropolitan area or region. Each employee should have a file that lists their cell phone number, personal email address, and emergency contact, if needed during the emergency event.

本书版权归John Wiley & Sons Inc.所有

Security

An individual should be assigned responsibility for providing direction to the staff regarding security and crowd control until the security personnel arrive in the affected area. Access to the laboratory is restricted to allow employees and emergency staff to respond to the emergency. The individual with temporary security duty provides information to security personnel and may determine whether to evacuate the laboratory.

Training

The EMP outlines an orientation and education program for facility personnel, including interaction with other emergency organizations in the region. The training addresses (i) specific roles and responsibilities during an emergency, (ii) the information and skills required to perform duties, (iii) the back-up communication system used during disasters, and (iv) the system to ensure that supplies and equipment are delivered where needed. The most important element of training is drills that are conducted to test whether the EMP works as anticipated. A challenging aspect of emergency planning and training is the assignment of responsibilities to the various participating community agencies and organizations, especially when there are competing agendas among the groups.

Monitoring and Evaluation

The EMP must address ongoing monitoring of performance regarding staff knowledge and skills, level of staff participation, inspection activities, incident reporting, and interagency cooperation. The Joint Commission requires that an EMP be activated yearly. Activation of the EMP may result from an actual disaster or as a planned exercise. The goal of the activation is to identify weaknesses in the program. An evaluation of the drill or emergency should be documented, and actions must be implemented to correct any deficiencies.

Disasters

Fire

All staff must be familiar with the potential fire hazards within the laboratory and be aware of the procedures necessary to ensure the safety of personnel in the area. These procedures include minimizing working supplies of flammable material, storing flammables in a flammable-safe cabinet, and identifying and controlling ignition sources. Training should emphasize response according to the RACE (rescue, alarm, confine, evacuate/extinguish) approach, sounding the alarm, knowing the preferred and alternative exit route from the work area (which may be dark and smoke-filled), using a fire extinguisher, knowing the fire codes, and closing all fire/smoke barrier doors. Fire extinguishers are classified by the type of fire that they will extinguish. Classifications are denoted by an initial. Most laboratories use a class C fire extinguisher, which is designed to combat fires involving live electrical equipment. When a fire is discovered, the RACE approach is as follows.

Rescue. Immediately notify others on the floor or in the area. Rescue any patients or victims in the fire area and close the door to the room or area involved. Do not reopen door.

Alarm. Activate the alarm by pulling the nearest fire alarm. Next, report the fire to the emergency center and give the location (room number, building, etc.) and the type of fire (type of material burning, how extensive, etc.). Generally, this information is relayed to the responding fire department so they can be prepared when they arrive.

Confine. Close all windows and doors on the floor as appropriate. Advise patients and visitors to keep the doors closed until notified otherwise. Keep calm and try to reassure patients. Check to make sure all fire/smoke barrier doors have been closed and are not blocked. Clear corridors.

Evacuate/extinguish. Attempt to extinguish only small fires. Do not attempt to fight large fires. Your best defense is to close the door and evacuate the immediate areas. When using a portable fire extinguisher, PASS guidelines should be followed (2):

- Pull the pin on the extinguisher.
- Aim the nozzle at the base of the fire.
- Squeeze the handle firmly.
- Spray in a sweeping motion.

Hazardous Materials

Hazardous materials are any substances cited as a health and physical hazard by the Occupational Safety and Health Administration (OSHA). Laboratory hazards are usually identifiable and quantifiable, and personnel should be knowledgeable about hazardous materials, be familiar with procedures to follow in an emergency, and be aware of measures to ensure the safety of personnel. Laboratories are required to maintain a chemical inventory list that identifies the type of hazard, the location, and the quantity present. This list should be posted in the laboratory and submitted to the facility's industrial hygienist and the local fire department. The plan should identify and assign responsibility to responders (i.e., safety officer, industrial hygienist) who can shut off utilities to prevent the spread of the hazard through the ventilation system and to

本书版权归John Wiley & Sons Inc.所有

minimize the potential for fire or explosions. Individuals must be trained to clean up spills and to decontaminate individuals exposed to chemical, radiation, or infectious agents. In addition, the telephone number for the regional hazmat team should be posted.

Generally, the industrial hygienist or safety officer can make a prompt evaluation of the hazard severity. Next action steps are then determined based on this initial assessment. The severity of the hazard is based on room size, type of chemical, and volume of material released. The decision to evacuate and notify the region's hazmat team is based on the evaluation of imminent danger to life or health as marked by injured or ailing personnel, symptoms of severe irritation, evidence of a large-volume spill, gas leaks, fire hazard, presence of carcinogens, or presence of very strong odors beyond the immediate area. When it can be done safely, individuals should be posted at entrances to prevent other people from entering the hazard area. As becomes possible, response personnel will disconnect any heat- or flame-generating equipment. The RACE approach to hazardous materials incidents should be followed.

- *Rescue*. Rescue only when applicable and safe to do so. Provide first aid (eye wash or showers) to victims and control access to the spill area.
- *Alarm*. Activate the emergency response system. Report the spill to the responsible person and provide relevant information such as who, what, when, where, and how much.
- *Confine*. Contain the spill, if possible, but only if trained to do so.
- *Evacuate*. Evacuate when there is immediate danger to life or health.

Radioactive Material

Sources of toxic, ionizing radiation in the laboratory include devices and reagents containing radioactive material. Laboratory policies should restrict access of untrained individuals from areas containing radioactive substances. The EMP should describe appropriate responses in the event of a spill, such as preventing spread by covering the spill with absorbent paper, limiting movement of contaminated individuals, shielding the radioactive source if possible, closing and locking the room, or otherwise securing the area. The affected individual is decontaminated by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. The involved area should be evacuated when the spill is large. Only trained persons should decontaminate an area, and they must wear protective clothing, gloves, and eye protection. After decontamination, the area must be checked for residual radiation. Each spill incident and decontamination must be documented by the appropriate safety personnel for radioactive material.

Utility Failure

Utility failures may be long or short in duration, may require an alternative means of providing service, or may require evacuation of the laboratory or facility.

Water. The EMP must address the need for emergency water for both equipment and potable water. The Department of Homeland Security (www.ready.gov) recommends 1 gallon of water per person per day and at least a 3-day supply. The potable water should be replaced every 6 months (www.redcross.org). Areas requiring water must be prioritized, and nonessential water consumption must be curtailed.

Electrical. Because loss of electrical power can paralyze a modern clinical laboratory, essential equipment must be attached to lines powered by emergency generators. Battery-powered lighting must be available if emergency generators fail, so that employees can safely exit the premises. Plans must anticipate the loss of ventilation and airflow to chemical and biological safety cabinets (BSCs). Loss of ventilation in the laboratory may cause instruments to overheat and accumulate noxious or toxic fumes. Inoperative chemical hoods and BSCs prevent the performance of procedures requiring their use. BSCs should have a safety mechanism that automatically prevents backflow of air through the filter when the fan shuts off.

Sewer. The EMP should address a failure in the sewer system due to lack of water or inability to discharge effluent. Priority is given to infection control measures (e.g., handwashing), direct patient testing, and meal preparation.

Bomb Threat

All threatening telephone calls should be taken seriously. The employee must remain calm, attempt to keep the caller on the line without increasing his or her antagonism, record details of the call, and notify police immediately. Often, a colleague can notify the security personnel while the first employee talks to the caller. Security personnel will decide whether the facility should be evacuated.

Active Shooter/Hostage Response

Unfortunately, the possibility of an active shooter has become reality. Doors into the laboratory areas should all be secured with badge and/or keypad. Text messages and/or overhead announcements with code word(s) for active shooter and instructions must be immediately relayed. Policy should be developed to address how to alert all individuals, when to evacuate versus hide, and last-resort efforts like confronting shooter.

本书版权归John Wiley & Sons Inc.所有

Natural Disasters

Earthquakes, tornadoes, floods, hurricanes, and similar weather-related disasters usually arrive with little warning and can have a major impact on the hospital or clinic and the surrounding community. The EMP should contain definitions of storm warnings used in the local area, provide instructions for employees (e.g., take cover under sturdy furniture or in a doorway during initial earthquake shaking), and establish an early release from work for nonessential employees. When structural damage is suspected, clinical operations should not resume until a qualified inspection of the premises has occurred. The effects of a natural disaster include damage to the facility, interruption of communications, inability of employees to leave or return to the facility, and injured individuals requiring treatment. Initially, a survey of the area should be performed to identify trapped people, structural damage, inoperative equipment or systems, unsafe or unhealthful conditions, and hazardous locations. Damaged containers of chemicals must be removed, and infectious material must be bagged and safely discarded. Visitors, patients, and employees within a dangerous area should be evacuated.

Pandemics

In the past, several pandemics or emerging pathogens have affected the clinical laboratory in different ways. For example, in the blood bank laboratory, as pathogens emerge such as HIV-1 and HIV-2, *Babesia* spp., *Trypanosoma cruzi*, and West Nile virus, the need to test the blood supply for these pathogens has become a necessary requirement. When the influenza H1N1 outbreak occurred in 2009, laboratories had a significant increase in volume for respiratory testing that often required additional instrumentation and in many instances space for instrumentation. However, in the case of this H1N1 outbreak, the core clinical laboratory was minimally impacted. In contrast, the SARS-CoV-2 pandemic stressed the clinical laboratory more than has been experienced previously. There was real fear about the infectiousness of the organism and how to protect laboratory employees. Such concerns resulted in the scheduling of several in-services to discuss the nature of the virus and what should be done to prevent infection, as well as what protective measures to use when working with potentially infectious specimens. Once testing was commercially available, assays had to be validated quickly and personnel were trained to perform these tests, often around-the-clock daily. Supply chain issues were oppressive at the apex of the pandemic and to date, laboratories continue to struggle with supply shortages. While microbiology and molecular laboratories were dealing with shortages of collection devices, plastic consumables, testing reagents, and bacterial media, the core laboratory was also struggling with plastic consumables and the ability to obtain blood collection tubes. The test menus were altered based on available supplies and testing reagents, for which these changes had to be communicated to stakeholders. Depending on the availability of collection devices, specimen collection guidelines had to be updated often and that information had to be communicated not only to the laboratory but also to clinicians and nursing staff. Supplies were in such short supply that some institutions opted to manufacturer their own collection devices and transport media. Additionally, personnel were being shifted around to meet the demands of testing per that department. All these issues demonstrated the need for laboratories to be able to pivot their personnel, testing capacity, supply shortages, and test menu. While many institutions had management continuity plans in place to cover some of these issues, most laboratories were not prepared for the duration of sustaining the supplies/personnel that became necessary for this pandemic response.

Terrorism Threats

Terrorism threats pose a very complex problem for laboratories, facilities, communities, and the nation. Sources of expert information on chemical and biological agents should be readily available (Appendix 26.4). The laboratory EMP must outline procedures for handling terrorism material (e.g., chemical, radiological, or biological) in the laboratory and for managing a large number of walk-in patients and subsequent clinical specimens (Appendix 26.4) (5–9). Key elements of an effective terrorism EMP include issues such as prompt recognition of an event; identification of individuals who are first responders (e.g., staff who have received smallpox vaccination), staff, and facility security; obtaining assistance from community and federal agencies (e.g., hazmat teams, FBI, local police, CDC, state laboratory); coordination of activities with other external emergency response agencies or organizations; release of public information; and decontamination plans for patients and staff. The administration should address physical security, airflow and ventilation, and maintenance of the facility's structure (10). Security officers must plan for crowd control, directing the flow of casualties and vehicles, and preventing unauthorized entry to decontamination and treatment areas. Plans need to be in place to rotate staff into work areas and to provide food, psychological support, and rest for employees.

The CDC's Bioterrorism Preparedness and Response Program addresses a unified public health response to bioterrorism events that includes measures for disease surveillance, laboratory diagnosis of biological agents, communication between various public health authorities, epidemiological investigations, and readiness assessments (https://emergency.cdc.gov/bioterrorism). The Laboratory Response Network links local, state, federal, military, veterinary, and environmental laboratories

本书版权归John Wiley & Sons Inc.所有

and classifies laboratories based on their anticipated role in the event of a biocrime or bioterrorism event and on their capacity to safely handle and identify agents of bioterrorism (11–13). The original Laboratory Response Network model involved four levels of laboratories (levels A, B, C, and D) but currently contains three classification levels (sentinel, reference, and national laboratories). Sentinel laboratories (formerly level A) include most clinical and commercial laboratories, whose function is to recognize, rule out, and refer potential agents to the reference laboratories (formerly levels B and C). Reference laboratories are generally local or state public health laboratories, whose function is confirmatory testing and processing of environmental samples. There are presently only a limited number of national laboratories (CDC, U.S. Army Medical Research Institute of Infectious Diseases, National Emerging Infectious Diseases Laboratory [Boston University], Rocky Mountain Laboratories [in association with the National Institute of Allergy and Infectious Diseases {NIAID}, and Galveston National Laboratory University of Texas Medical Branch at Galveston]) that can operate at a biosafety level 4 capability.

Clinical microbiology laboratories must develop protocols for the recognition and identification of the potential agents of bioterrorism and procedures for management of these events. These protocols should be part of the routine bench procedures so that potential agents are not misidentified or improperly handled and can be rapidly referred to a reference laboratory for confirmation (14). Protocols developed by authorities are available on various websites (https://emergency.cdc.gov/bioterrorism; https://asm.org/Articles/CPHMC/Laboratory-Response-Network-LRN-Sentinel-Level-C) and in publications (11, 12). Sentinel laboratories should not process specimens for smallpox or viral hemorrhagic fever from high-risk patients. These samples should be sent to the CDC after consultation with the state public health division. Instructions for the collection and shipment of specimens for smallpox can be found at https://www.cdc.gov/smallpox/lab-personnel/specimen-collection/specimen-collection-transport.html. In addition, sentinel laboratories should not process environmental samples (e.g., suspicious powder for *Bacillus anthracis* spores) or animal specimens but rather should contact the FBI and reference laboratory for instructions. Often the latter samples involve a chain-of-custody procedure.

Civil Disorder

In most situations, the local law enforcement agency is aware of planned demonstrations and arranges for control measures. Unplanned acts of civil disturbance are handled by the facility security personnel in cooperation with the local law enforcement agency. An effective communication system must be in place to keep the employees and public informed.

SUMMARY

Emergency preparedness planning and management must involve the entire healthcare organization, the community, and with the present threat of terrorism, the nation. Effective disaster planning requires anticipation of any type of disaster that prevents the laboratory from providing services. The laboratory manager may be involved in overall disaster recovery, providing laboratory resources as needed for patient care and facility support. Disasters can be external (e.g., weather, failures in transportation services) or internal (e.g., facilities breakdowns, equipment malfunctions, lack of personnel). Consideration should be given to the impact on laboratory personnel, depending on the nature of the disaster. Planning, preparation, and communication will improve the laboratory's response to a disaster if one should occur.

KEY POINTS

- Disasters may stem from a variety of root causes but result in consistent impact on operations—failure to provide services.
- EMPs should be comprehensive and included in laboratory policy and procedures.
- Guidelines are available from many resources, based on local, regional, and national regulations.

GLOSSARY

Biohazard An agent of biological origin that has the capacity to produce deleterious effects on humans, e.g., microorganisms, toxins.

Disaster Any incident that interferes with a facility's ability to operate in a normal manner.

Emergency A natural or human-caused event that suddenly or significantly disrupts the environment of care, disrupts care and treatment, or changes or increases demands for the organization's services.

EMP Acronym describing emergency management plan. This plan is a comprehensive document that defines the scope of the program and lists responsible individuals.

External disaster An event external to the physical laboratory location that may affect operations by limiting available staff or supplies or changing laboratory workload (e.g., influx of patients, uncommon tests required). Examples include major storms, earthquakes, transportation accidents, or acts of terrorism.

Facility A healthcare organization (hospital, clinic, physician's office) that includes an on-site laboratory.

Hazardous material A substance or material that has been determined by the U.S. Department of Transportation to pose an unreasonable risk to health, safety, and property when transported in commerce.

本书版权归John Wiley & Sons Inc.所有

Hazmat team Group of individuals who are trained to respond to and clean up hazardous material spills.

Internal disaster An internal event within the laboratory or facility that affects patient care and facility operation, including power failure, hazardous chemical spill, fire, or lack of personnel.

Laboratory A facility that provides services including specimen collection, testing, and results reporting.

RACE Acronym describing the appropriate approach by first responders to a fire or disastrous situation: rescue, alarm, confine, evacuate/extinguish.

Reference laboratory An on- or off-site laboratory performing tests on behalf of a clinical laboratory or facility, typically including rare or esoteric test menus.

Service levels Test menu, results reporting, and ancillary assistance provided by the laboratory to hospitals, clinics, physicians, and patients.

REFERENCES

1. **Merriam-Webster**. 1998. *Webster's American College Dictionary*. Random House, New York, NY.

2. **Tweedy JT**. 2005. *Healthcare Hazard Control and Safety Management*, p 121–155, 2nd ed. CRC Press, Boca Raton, FL.

3. **College of American Pathologists**. 2012. *Laboratory Accreditation Program, Laboratory General Checklist*. College of American Pathologists, Northfield, IL.

4. **The Joint Commission**. 2012. *Laboratory Accreditation Standards*. The Joint Commission, Oakbrook Terrace, IL.

5. **Londorf D**. 1995. Hospital application of the incident management system. *Prehosp Disaster Med* **10**:184–188.

6. **Macintyre AG**, **Christopher GW**, **Eitzen E** Jr, **Gum R**, **Weir S**, **DeAtley C**, **Tonat K**, **Barbera JA**. 2000. Weapons of mass destruction events with contaminated casualties: effective planning for health care facilities. *JAMA* **283**:242–249.

7. **U.S. Department of Health and Human Services**. 1996. *Health and Medical Services Support Plan for the Federal Response to Acts of Chemical/Biological (C/B) Terrorism*. U.S. Government Printing Office, Washington, DC.

8. **U.S. Army Medical Research Institute of Chemical Defense**. 2000. *Medical Management of Chemical Casualties Handbook*, 2nd ed. U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD.

9. **U.S. Army Medical Research Institute of Infectious Diseases (ed)**. 2011. *Medical Management of Biological Casualties Handbook*, 7th ed. U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD.

10. **National Institute for Occupational Safety and Health**. 2002. *Guidance for Protecting Building Environments from Airborne Chemical, Biologic, or Radiological Attacks.* DHHS publication no. NIOSH2002-139. U.S. Government Printing Office, Washington, DC.

11. **Gilchrist MJR**, **McKinney WP**, **Miller JM**, **Weissfeld AS**. 2000. Cumitech 35, Laboratory safety, management, and diagnosis of biological agents associated with bioterrorism. Coordinating ed, Snyder JW. ASM Press, Washington, DC.

12. **Miller JM**. 2001. Agents of bioterrorism. Preparing for bioterrorism at the community health care level. *Infect Dis Clin North Am* **15**:1127–1156.

13. **Snyder JW**. 2003. Role of the hospital-based microbiology laboratory in preparation for and response to a bioterrorism event. *J Clin Microbiol* **41**:1–4.

14. **Shapiro DS**, **Schwartz DR**. 2002. Exposure of laboratory workers to *Francisella tularensis* despite a bioterrorism procedure. *J Clin Microbiol* **40**:2278–2281.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 26.1 List of Selected Emergency Preparedness Agencies and Organizations

Governmental Agencies
Centers for Disease Control and Prevention
Domestic Preparedness Information Line
Federal Bureau of Investigation
Federal Emergency Management Agency
Homeland Security Operations Center
National Centers for Environmental Predictions
National Hurricane Center
National Oceanic and Atmospheric Administration
National Response Center
National Weather Service
U.S. Army Corps of Engineers
U.S. Geological Survey National Earthquake Information Center
U.S. Public Health Service

Nongovernmental Organizations
American Red Cross
Church charities
Corporation for National Service (disaster services)
National Emergency Management Association
Salvation Army

APPENDIX 26.2 Emergency Operations Center (EOC) Checklist

_____ Determine status of the emergency and implement management as appropriate.

_____ Set up EOC in the designated area. Determine the presence of key personnel for EOC and triage area.

_____ Establish command activity and direct all emergency relief activities.

_____ Identify the departments needed to support the relief activity and ensure that each department knows what is expected of them.

_____ Ensure that the triage area is functioning.

_____ Ensure that appropriate call-back is progressing, and all necessary supplies are delivered to the triage area. Utilize personnel pool to ensure that appropriate assistance is maintained.

_____ Request necessary assistance from state or local agencies (i.e., fire, police, ambulance, bomb squad, hazmat team, etc.).

_____ Notify other divisions of the emergency and request aid or place staff on standby.

_____ Brief all individuals reporting to the EOC. Dismiss individuals that are not required for the relief effort.

_____ Ensure that all departments (e.g., security, safety) that automatically respond to external and internal emergencies are notified and responding.

_____ Ensure that internal communication is established.

_____ Ensure that recorders are assigned to key response functions to document activities for the incident manager.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 26.3 Operating Status Report Form

Name of hospital: _____

Date/time report given: _____

Contact person: _____

Title/location: _____

Contact method: _____

Contact number: _____

			Questions	Comments
1.	Y	N	Can you continue to treat incoming patients?	If no, why not?
2.	Y	N	Any patients evacuated to outside the hospital?	If yes, why? Total # evacuated # unstable or critical patients
3.	Y	N	Any patients or staff injured?	# of injured people. Deaths?
4.	Y	N	Any structural damage?	Partial or total collapse?
5.	Y	N	Any major non-structural problems?	List
6.	Y	N	Power from any source?	
7.	Y	N	Can generator power essential areas?	
8.	Y	N	Can you communicate with the outside world?	
9.	Y	N	Access to all essential areas?	Anyone trapped?
10.	Y	N	Sufficient number of elevators working?	
11.	Y	N	Water lines intact to essential areas?	
12.	Y	N	Natural gas lines intact to essential areas?	
13.	Y	N	Sewage system intact in essential areas?	
14.	Y	N	Adequate staff at the hospital?	What do you need?
15.	Y	N	Adequate supplies and equipment?	What do you need?
16.	Y	N	Have reagents and/or equipment been compromised from disaster (extreme heat or cold, water-damage, etc.)	Reagents and/or instruments will need re-verification studies performed before patient testing can be performed
17.	Y	N	Any outside assistance needed?	What?
18.	Y	N	Need structural engineer?	

本书版权归John Wiley & Sons Inc.所有

APPENDIX 26.4 Selected Information Resources on the Internet

EMERGENCY PREPAREDNESS WEBSITES

Federal Emergency Management Agency
https://www.fema.gov/ (accessed 9 October 2023)
http://www.ready.gov/are-you-ready-guide
https://www.ready.gov/biohazard
Source of materials for emergency preparedness

The Joint Commission
http://www.jointcommission.org
Guidelines on emergency management standards

National Institute for Occupational Safety and Health
http://www.cdc.gov/niosh
Resources on chemical agents and emergency preparedness

Occupational Safety and Health Administration
http://www.osha.gov
Training materials, standards, and regulations related to safety in the laboratory

Office of Health and Safety
http://www.cdc.gov/od/ohs
Resources on safety, biosafety, and safety survival

U.S. Government Printing Office
https://www.gpo.gov/
Source for federal regulations

BIOTERRORISM WEBSITES

American Society for Microbiology
http://www.asm.org
Training materials, laboratory protocols, and regulations related to bioterrorism preparedness

College of American Pathologists
http://www.cap.org
Links to other websites on bioterrorism preparedness

Centers for Disease Control and Prevention
https://www.cdc.gov/labtraining/training-courses/biothreat-preparedness-sentinel/index.html
Training materials, laboratory protocols, regulations, guidelines for laboratory and healthcare facilities preparedness

Department of Homeland Security
http://www.ready.gov
Information on preparedness for all terrorism events

Infectious Diseases Society of America
http://www.idsociety.org
Resources related to bioterrorism preparedness

U.S. Army Medical Research Institute of Infectious Diseases
https://usamriid.health.mil/
Reference material on biological and chemical warfare agents

本书版权归John Wiley & Sons Inc.所有

V

Financial Management

(SECTION EDITOR: **Michael R. Lewis**)

27 Financial Management: Setting the Stage
Lynne S. Garcia

28 Strategic Planning
Jonathan R. Genzen and Paul Valenstein

29 Human Resource Management in the Laboratory: An Important Component of Financial Management
Fred Westenfeld and Michael R. Lewis

30 Costs, Budgeting, and Financial Decision Making
Geoffrey C. Tolzmann, Richard J. Vincent, and Michael R. Lewis

本书版权归John Wiley & Sons Inc.所有

本书版权归John Wiley & Sons Inc.所有

27

Introduction
The Hospital Environment
Financial Challenges Created by the COVID-19 Pandemic • Operating in the Inpatient Hospital Setting • Operating in the Outpatient Hospital Setting
The Non-Hospital Environment
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENT
REFERENCES

Financial Management: Setting the Stage

Lynne S. Garcia

OBJECTIVES

To establish the importance of the environment in which the laboratory operates

To review the constraints placed upon management in the hospital and independent laboratory settings

To introduce the fiscal considerations that may be important for laboratory management in these settings

All the world's a stage,
And all the men and women, merely Players;
They have their Exits and their Entrances,
And one man in his time plays many parts ...

William Shakespeare, *As You Like It*, Act II, Scene VII

Statistics from June 2022 indicate that there are 317,247 clinical laboratories in the United States (1), including 123,896 laboratories located in physician offices. Of these, as of January 2022, 84,759 perform only Clinical Laboratory Improvement Amendments (CLIA)-waived testing (see Glossary), and 21,138 do only provider-performed microscopy. In contrast, there are 9,188 hospital laboratories. Of the remainder, 9,413 are independent. The U.S. clinical laboratory services industry revenue was estimated at $87 billion in 2017 (2) and $112 billion in 2021 (3). Table 27.1 summarizes the demographics of the laboratory industry.

This chapter concentrates on hospital and independent laboratories, which usually perform moderate- and high-complexity testing. As laboratory instrument and supply manufacturers innovate and improve their products, the number of high-complexity tests done in clinical laboratories has declined somewhat; it is obvious that the market incentives for manufacturers lie in simplicity and reliability of operations. The supply of individuals qualified to perform high-complexity testing has declined along with this lack of demand (although not solely for this reason; the number of schools training medical technologists/clinical laboratory scientists has also dramatically declined). In contrast, testing in most physician office laboratories is limited, of waived or moderate complexity, and performed by individuals whose primary training and responsibilities are not in laboratory medicine.

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch27.

本书版权归John Wiley & Sons Inc.所有

Table 27.1 Demographics of the laboratory industry[a]

Laboratory type	No.
Total clinical laboratories	317,247
Physician office laboratories	123,896
Performing CLIA-waived testing only	84,759
Performing provider-performed microscopy only	21,138
Other physician office laboratories	17,999
Hospital-associated laboratories	9,188
Independent laboratories	9,413
Others (includes public health, insurance, etc.)	174,750

[a] See reference 1. Figures are as of June 2022; physician office laboratory category data are from January 2022.

The most important contributors to financial performance in the laboratory industry are:

- Leadership
  - Operations management
  - Information management
  - Incorporation of new technologies
- Marketing
  - Laboratory specialty niches
  - Service area
  - Competition
  - Product availability/comprehensive information
- Customer service
  - Couriers
  - Phlebotomy
  - Client services
  - Billing and pricing
  - Availability of consultation/expertise
  - Accessibility of results to providers and patients
  - Overall response times
- Payor mix and policies
  - Network contracts (local and national)
  - Out-of-network policies

This section of the book deals with the operational management of the laboratory, including strategic planning, human resource management in the operational units, cost analysis, and financial decision making. Before discussing the details, it is worthwhile to consider the broad outlines of the challenges that face laboratory managers and workers in the industry as a whole and in the major segments.

The Hospital Environment

In the hospital institutional environment, the laboratory usually operates as a division under a vice president or director of operations. Along with other operational divisions, such as pharmacy and dietary, the laboratory must compete for resources with direct-patient-care divisions, such as nursing (Fig. 27.1). Because the laboratory may not be directly represented at the table where administrative and fiscal decisions are made for the institution, and because the work of the clinical laboratory is relatively invisible compared to direct patient care, it can be at a disadvantage in these negotiations. Consequently, it becomes even more important for laboratory management to be perceived as a team player in the hospital—to be seen as clinically responsive and fiscally responsible. These attributes become increasingly important when large capital expenditures or program expansions are sought.

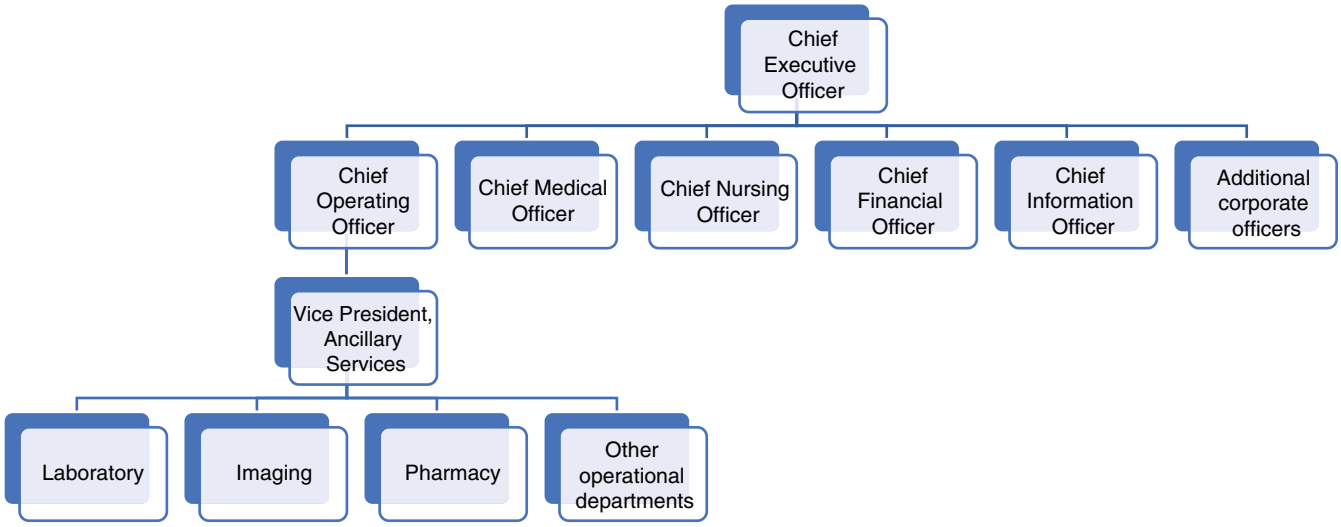


Figure 27.1 Organizational chart of a hospital that is organized in a traditional manner. Note that the chief operating officer, who is parallel in reporting responsibility to the chief nursing officer, is responsible for all ancillary services through a vice president who is responsible for various support services.

本书版权归John Wiley & Sons Inc.所有

In these financial situations, the role of the laboratory medical director is critical. To be most effective, the director must speak for the medical needs of patients, particularly as they relate to laboratory services, but must also present a credible front to the hospital administration when addressing the business aspects of the laboratory, such as budgeting, billing, and planning.

In certain sections of the laboratory, such as anatomic pathology and the blood bank, the director must be a physician. The directors of all sections—and especially the overall laboratory director—will be able to function most effectively, whatever their academic degree, if they have a medical or clinical background that gives them credibility with the medical staff. Similarly, the relationship with the hospital administration may be enhanced if the laboratory director has a business background or at least demonstrable competence in business matters, including awareness and understanding of the broader institutional context in which the laboratory operates.

The ideal director, who fully satisfies both sets of competencies, may be difficult to find. In fact, it is not essential that all that talent be manifest in one individual if the director can utilize other resources within the laboratory. It is essential, however, that the person at the top have a balanced view of the laboratory world.

Financial Challenges Created by the COVID-19 Pandemic

Challenges from the coronavirus disease 2019 (COVID-19) pandemic have created tremendous financial pressures for hospitals: cancellation of nonemergency procedures, increased demand for certain medical equipment and supplies, the disruption of supply chains, increased job losses, more uninsured, and additional support for employees. Healthcare providers are also concerned that patients are neglecting important care, such as chronic disease management, which can further complicate their overall health status. As a result of all of these factors, there have been substantial revenue reductions for all hospitals across the country. Although the hospital and independent laboratory environments differ in many ways, all testing sites will be impacted by the current financial pressures throughout the healthcare system.

Operating in the Inpatient Hospital Setting

The major differences in the cost and operational structures of independent and hospital laboratories lie in the patient populations and the nature of the services provided. The two are dramatically different in their institutional missions, patient populations, hours of operation, percentage of tests requiring rapid turnaround (STAT testing), communication and reporting requirements, and the need for highly specialized testing. In this section, we explore the environment of the hospital laboratory and how these factors may affect financial performance (Table 27.2).

Table 27.2 Components of diagnostic laboratory testing[a]

Category of testing	Examples
STAT; immediate response required	Blood gases; frozen sections
Intermediate response; same day or shift	Routine chemistry and hematology
ASAP response; depending on technology	Microbiology, surgical pathology, molecular testing

[a] There may be STAT situations within every diagnostic laboratory testing site; this information represents typical components within each category.

Hospital laboratories have primary responsibility for an inpatient population of seriously ill people. Much clinical care has shifted to the outpatient environment, and length of hospital stays has dramatically decreased in the United States since the introduction of diagnosis-related reimbursement. As a consequence, the acuity of illness of hospitalized patients has increased. More than ever, hospital laboratories must dedicate significant resources to 24-hours-per-day, 7-days-per-week support for critically needed testing, often with a rapid turnaround time, to care for these patients. The simultaneous requirement to support the care of an increasing population of patients who are seeking emergent care further adds to the burden.

In this environment, the primary mission of the institution requires staffing, procedures, and instrumentation that support rapid production of testing results around the clock. The financial consequence of this mission is relatively low productivity for both instruments and personnel; as a consequence, costs are relatively high. Fortunately, the per-unit cost of equipment and reagents for most of the required tests is low. Additionally, economies can be achieved if additional nonemergent testing can be used to fill excess capacity.

The high-acuity setting also leads to its own set of requirements for communication and information technology. The frequent need to transmit highly abnormal results to clinicians who care for critically ill patients often requires staff to leave the workspace, both to call in results on the telephone and to answer requests for results. As the laboratory obtains more critically abnormal results, more tests must be repeated or additional procedures must be performed.. Balancing the demanding requirements for testing among sites with critical needs, such as intensive care units and emergency departments, often becomes very difficult. Table 27.3 summarizes the factors that detract from the efficiency of hospital-based laboratories.

Depending on their size, hospital laboratories find it financially feasible to add batch processing for tests that do not require rapid turnaround times. Cutting-edge technology, such as molecular diagnosis and molecular genetics, does not

本书版权归John Wiley & Sons Inc.所有

Table 27.3 Factors that produce inefficiency in hospital-based laboratories that serve inpatients[a]

Requirement for rapid laboratory response
Necessity for frequent repetition of tests
Need to telephone emergent or critical results to providers
Lack of integrated information systems
Supply chain issues in particular circumstances (e.g., COVID-19 pandemic)
Personnel shortages
Limited automated options

[a] Some of these factors may also be seen in independent laboratories.

at present require immediate responses—although as technology improves, this is likely to change. Thus, these laboratories tend to have a portion of their staff devoted to relatively low-complexity, rapid-turnaround testing operating around the clock and a second component of staff devoted to batch production of relatively high-complexity testing that requires special expertise, high-cost reagents or instrumentation, and longer turnaround times (4). It should be noted that even in the rapidly expanding arena of molecular testing, pressure is growing to produce speedy results using real-time amplification technologies. Molecular diagnostic techniques and platforms continue to play an expanded and more critical role in sections within anatomic and clinical pathology. Based on this expansion of molecular capabilities, clinical laboratories have seen a dramatic increase in their test menu options based on DNA and RNA analysis.

The two components of staff needed for low- and high-complexity testing are usually not interchangeable. Cross-coverage for vacations, illness, or other mandated benefits, such as training and continuing education, is impractical because the skill sets (and mindsets) for the two forms of testing are so different. Therefore, the larger and more complex the laboratory, the less likely it is that individual employees will be able to cover both low- and high-complexity testing.

After personnel costs, reagent and supply costs are the second-largest component of laboratory costs. There is a clear relationship between laboratory size, as measured by test volume, and supply costs. Larger laboratories have lower per-test supply costs than do smaller laboratories. The relative decrease in the cost of consumables with increases in laboratory size often occurs because larger purchasers get better pricing from suppliers; this effect may be magnified for hospital-based laboratories by the hospital's (or health system's) contract with a group purchasing organization.

Reimbursement of hospitals for inpatient stays is based on one of the following schemes, depending on the payor (Table 27.4):

- *Percent of charges:* Contractually negotiated by the hospital with payors

Table 27.4 Reimbursement mechanisms in the inpatient, outpatient, and independent laboratory settings

Inpatient laboratories	Outpatient and independent laboratories
Diagnosis-related groups (DRGs)	Percent of charges
Per diem	Fee schedule
Percent of charges	Capitation
	Ambulatory payment classification groups (APCs)

- *Per diem:* A per-day negotiated rate which represents an allowance that includes all services for that day.
- *Reimbursement for diagnosis-related groups (DRGs):* A case-mix complexity system implemented to categorize patients with similar clinical diagnoses in order to better control hospital costs and determine payor reimbursement rates.

The second and third of these schemes are the most common in the United States, where reimbursement based on charges has largely disappeared for inpatients (an exception being Medicare reimbursement of critical-access hospitals). As discussed above, payment schemes affect the financial performance of hospital laboratories in complex ways. For example, the intent of diagnosis-based reimbursement for hospital care is to create incentives for hospitals to minimize unneeded expenditures for all aspects of hospital care (commonly measured as length of stay), including laboratory testing (5). The efficacy of this incentive is illustrated by the substantial decrease in length of hospital stay for all hospitals, from 10 days in 1980 (before DRGs) to approximately 6.1 to 6.2 days from 2009 through 2019 (6). Current figures indicate that the length of stay was 5.4 days in 2021 (7). Certainly, the pandemic must be considered when interpreting the increased figure for 2021. Generally, reimbursement for care of hospitalized patients that is not driven by DRGs is done on a per diem basis.

For the laboratory, the consequence of both payment schemes is that inpatient revenue is unrelated to the quantity of testing. The institution gains if the length (cost) of stay declines and if the number of laboratory tests done on each inpatient is reduced. In this scenario, however, physicians are faced with the need to care for increasingly ill patients in less time. It is estimated that upwards of 70% of the patient data in hospitals comes from the clinical laboratory. The bulk of laboratory testing during a hospital admission occurs in the first few days, when the patient is most acutely ill and when diagnoses are being tested and rejected or established by clinicians. The financial gain for the laboratory produced by earlier discharge after these initial intensive days may, therefore, be minimal. Pressures to reduce length of stay will tend to compress the same

本书版权归John Wiley & Sons Inc.所有

amount of testing into a shorter period, leading to little if any reduction in laboratory costs (8).

Laboratory administrators are often surprised by the amount of indirect costs borne by the laboratory in the hospital setting. The laboratory is one of the few hospital departments that bills for services directly; other charges include those for pharmaceuticals, medical supplies, and "hotel" functions (bed charges). The simplest way to approach these costs is to examine the hospital's annual Medicare cost report, which allocates all indirect costs in a uniform way to departments. Often, direct laboratory costs for labor and supplies may be only half of total costs, with the remainder resulting from these charges for institutional indirect costs (4).

Operating in the Outpatient Hospital Setting

Many hospital laboratories, especially those in academic medical centers, serve significant numbers of outpatients. These encounters with the outpatient facility may be associated with prior or future inpatient stays, for example, before or after surgical procedures. Here, one might suppose the demand for rapid turnaround times must be less than that in the inpatient setting. In fact, the need for high-volume outpatient clinical operations is as varied and complex as the inpatient operations. In some situations, the need for rapid turnaround of test results may be surprising—it results from the increasing shift of sophisticated patient care from the hospital ward or operating room to the outpatient medical clinic, dialysis unit, or surgery center. Oncology clinics, for example, often need the results of laboratory testing to decide if and at what dose a patient may receive chemotherapy that day. The complexity and sophistication of testing in this environment actually tend to be higher than in the inpatient setting; complex endocrinologic diagnoses, for example, are usually sought in the outpatient setting. However, in this instance, the tests do not usually require rapid turnaround and are best batched.

Hospital reimbursement in the outpatient setting is based on (Table 27.4):

- *Percent of charges:* Contractually negotiated by the hospital with payors
- *Fee schedule:* Contractually negotiated with payors or as prescribed by the government for Medicare
- *Capitation:* Managed care reimbursement that prepays providers for services on a per-member per-month basis whether or not services are used.
- *Ambulatory payment classification groups (APCs):* An outpatient service or group of services for which a single rate is set. The government's method of paying facilities for outpatient services for the Medicare program.

The first two methods are straightforward and traditional. Capitation first appeared to any significant degree after the failed Clinton-era attempt at reconstruction of healthcare. Health maintenance organizations and other payors found that their market power enabled them to demand favorable, often capitated contracts from providers in many areas of the country. At one point, capitation of laboratory testing was paid at $0.60 per member per month in some areas. Over the past 15 years, as excess capacity has been wrung out of the healthcare system, providers have regained some of their market power, and the pendulum has swung back toward the first two approaches. Medicare now reimburses hospital outpatient services based on APCs, which are a clone of the Medicare physician payment system.

In this outpatient arena, hospital laboratories compete with the commercial laboratory sector for business. In recent years, the market share of hospital laboratories has increased at the expense of the commercial sector, though commercial laboratories have increasingly sought to manage or purchase hospital laboratories. While serving hospital outpatients has its own set of service demands, as indicated earlier, hospital laboratory outreach programs require, in addition, marketing, courier, and phlebotomy services, business services such as billing and accounting, and customer support. Hospital laboratories often have excess technical capacity for testing, resulting from their need for rapid turnaround and their diurnal variation in demand (highest during the day and lowest at night). The unused capacity in the evening may allow the addition of outreach testing at minimal marginal cost. While most hospitals in the United States are still not for profit, laboratory operations in the for-profit sector are basically similar to those in the not-for-profit sector.

The Non-Hospital Environment

The breadth of testing provided by independent laboratories generally mirrors that of hospital-associated laboratories. The major differences lie in the population served, hours and scope of operation, turnaround time requirements, and need for ancillary functions, such as business operations. Some of these facilities do a substantial amount of reference (esoteric) testing for hospitals and other laboratories.

Most of the testing done by the independent laboratories is for outpatients seen in ambulatory settings (e.g., clinics). Some may provide phlebotomy services at or near the offices and clinics they serve. Essentially all provide couriers for the transportation of specimens back to the home laboratory. Except for work that requires rapid turnaround, which is unusual in this setting, most specimens are transported during daylight hours and arrive at the laboratory in the evening or at night. Thus, the major

本书版权归John Wiley & Sons Inc.所有

testing effort takes place during the night in one large batch, and most results of routine tests are transmitted before the physicians' offices open the next morning.

This type of workload and scheduling influences the laboratory's staffing pattern and even its instrumentation choices. For example, the setting requires batch instrumentation that can process large numbers of samples relatively expeditiously but with no need for rapid turnaround of any individual sample. An instrument that operates in a batch mode, then, may be better suited to this setting than one that may be somewhat slower but allows the interposition of STAT samples at any time. To the extent that these laboratories do esoteric work, for which a longer turnaround time of up to 4 or 5 days is often acceptable, that work is usually done separately during a smaller day shift. If the marketplace justifies provision of the service, some independent laboratories perform forensic, veterinary, or environmental testing. A number of highly specialized niche laboratories operate in still other areas, such as cytogenetics, molecular genetics, forensic toxicology, and other areas that large national laboratories were reluctant to enter because of cost or need for specialized expertise. However, the larger reference laboratories currently provide extensive testing in all of these areas.

For the most part, independent laboratories serve an outpatient population. To be sure, in some (mostly rural) areas, an independent laboratory may contract with a local hospital to supply laboratory services. The reimbursement schemes for this sector of the industry are the same as those listed above for hospital outpatient work (Table 27.4). Major requirements for these laboratories include, in addition to the aforementioned courier and phlebotomy services, medical consultation, billing, accounting, client relations, marketing, sales, and information services functions. In the hospital setting, these functions are usually performed mostly outside the laboratory.

The small independent laboratory has the advantage of flexibility and the ability to move quickly to adapt to the market; it is not burdened with hospital administrative overhead and cumbersome decision-making processes. Of course, management decisions are reflected rapidly in the bottom line, for better or worse. Because diagnosis-related reimbursement is usually not an issue in this market segment, and because the prevalence of capitation has been declining, it is in the interest of the independent laboratory to maximize laboratory utilization and thus revenue.

Significant numbers of independent laboratories have undergone consolidation in response to market pressures in recent years; key factors influencing additional mergers and acquisitions are cost cutting and the increasingly competitive environment. Operating in the corporate setting involves less local autonomy and more centralized decision making. Local choices of tests offered, instrumentation, reagents, and so forth are likely to be very limited. On the other hand, the corporation will supply a centralized purchasing capability and likely similar data processing functions, releasing the local branch from these duties. On the revenue side, while the small independent laboratory must negotiate with providers or with payors who still permit local contracting, the large national corporations negotiate national contracts with payors when possible.

SUMMARY

The objectives of laboratory management must reflect the demands of the laboratory's clients and the clinical and financial environment in which it operates. There are fundamental and striking differences in clinical need and demand, financial constraints and considerations, and laboratory mission and cost structures, depending on the laboratory's situation. Whether hospital inpatient, hospital outpatient, or independent laboratory, each has its own set of functional drivers of which laboratory management must be acutely conscious.

KEY POINTS

- The demands for capable, effective management differ in the hospital inpatient, hospital outpatient, and independent laboratory settings.
- Laboratory management must be able to demonstrate intimate knowledge not only of the clinical needs for laboratory testing in various situations but also of the fiscal constraints of the institution in which it operates and be able to communicate this understanding to higher administration.
- Reimbursement mechanisms vary according to setting, and laboratory management must have a clear understanding of all of the relevant mechanisms, payor requirements, and limitations.

GLOSSARY

Ambulatory payment classification groups (APCs) An outpatient service or group of services for which a single rate is set; the government's method of paying facilities for outpatient services for the Medicare program.

Capitation Managed care reimbursement that prepays providers for services on a per-member per-month basis whether or not services are used.

CLIA '88 The Clinical Laboratory Improvement Amendments of 1988 and their implementing regulations, as published since 1992.

CLIA-waived testing A category of laboratory test complexity under CLIA (q.v.) which applies to tests that (i) are cleared by the U.S. Food and Drug Administration for home use, (ii) employ methods that are so simple and accurate as to render the likelihood of erroneous results negligible, or (iii) pose no reasonable risk of harm to the patient if the test is performed incorrectly.

本书版权归John Wiley & Sons Inc.所有

Fee schedule Contractually negotiated with payors or as prescribed by the government for Medicare.

Percent of charges Contractually negotiated by the hospital with payors.

Per diem A per-day negotiated rate which represents an allowance that includes all services for that day.

Provider-performed microscopy A category of moderate-complexity tests under CLIA (q.v.) involving a patient care provider using a microscope for testing, such as urine microscopic examinations.

Reimbursement for diagnosis-related groups (DRGs) A case-mix complexity system implemented to categorize patients with similar clinical diagnoses in order to better control hospital costs and determine payor reimbursement rates.

ACKNOWLEDGMENT

This contribution is based on the chapter of the same title by Ronald J. Lepoff in the second edition of *Clinical Laboratory Management*.

REFERENCES

1. **Centers for Medicare and Medicaid Services**. 2022. CLIA statistical tables/graphs. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Statistical_Tables_Graphs.html. Accessed 11 July 2022.

2. **CMS**. 2018. Examining clinical laboratory services. https://www.cms.gov/files/document/download-clinical-laboratory-services-white-paper.pdf. Accessed 11 July 2022.

3. **BusinessWire**. 2022. Global Clinical Laboratory Services Market Report 2022: Clinical laboratories played a vital role in response to the pandemic by ramping up capacity to meet the increased demand for Covid-19 testing – ResearchandMarkets.com. https://www.businesswire.com/news/home/20220527005371/en/Global-Clinical-Laboratory-Services-Market-Report-2022-Clinical-Laboratories-Played-a-Vital-Role-in-Response-to-the-Pandemic-by-Ramping-Up-Capacity-to-Meet-the-Increased-Demand-for-Covid-19-Testing---ResearchAndMarkets.com. Accessed 26 July 2023.

4. **Travers EM**. 1997. *Clinical Laboratory Management*. Williams & Wilkins, Baltimore, MD.

5. **Centers for Medicare and Medicaid Services**. 2012. Acute inpatient PPS. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html. Accessed 30 August 2012.

6. **Centers for Disease Control and Prevention, Health, United States.** 2020–2021. Table HospAdmis. Hospital admission, average length of stay, outpatient visits, and outpatient surgery, by type of ownership and size of hospital: United States, selected years 1980–2019. https://www.cdc.gov/nchs/data/hus/2020-2021/HospAdmis.pdf. Accessed 8 August 2023.

7. **OECD**. 2022. Length of hospital stay. https://data.oecd.org/healthcare/length-of-hospital-stay.htm. Accessed 11 July 2022.

8. **Valenstein PN**, **Praestgaard AH**, **Lepoff RB**. 2001. Six-year trends in productivity and utilization of 73 clinical laboratories: a College of American Pathologists Laboratory Management Index Program study. *Arch Pathol Lab Med* **125**:1153–1161.

本书版权归John Wiley & Sons Inc.所有

28

Introduction

Business Strategy and Operational Efficiency

Developing and Maintaining a Business Strategy: The Strategic Planning Process

Structure of the Clinical Laboratory Industry

The Testing Market • Concentration of Competitors • Barriers to Entry • Separation of Payor, Purchasing Agent, and Beneficiary • Economies of Scale • Restrictions on Markups and Kickbacks • Powerful Sellers and Buyers • Substitute Products • Unique Economics of Inpatient Care • Conclusions

Competitor Analysis

Competitors' Goals • Competitors' Assumptions • Competitors' Capabilities • Interactions of Competitors • Conclusions

Strategic Positions in the Clinical Laboratory Industry

What Are Strategic Positions? • Types of Strategic Positions • Strategic Positions of Clinical Laboratories • Conclusions

Implementing the Strategy: Activity Fit

What Is Activity Fit? • Activity Fit Involves Trade-Offs

Failure of Strategy

Straddling • Growth Trap • Profitability Trap • Hubris

SUMMARY

KEY POINTS

GLOSSARY

REFERENCES

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch28.

Strategic Planning

Jonathan R. Genzen and Paul Valenstein

Competitive strategy is about being different. It means deliberately choosing a different set of activities to deliver a unique mix of value.

Michael E. Porter

Business strategy is about equipping an organization to withstand competitive market forces. Business strategists concern themselves with understanding the structure of the industry and their competitors, defining unique market positions for the laboratory, and creating interlocking processes that provide the laboratory with a sustainable competitive advantage in its target markets. Whereas an operational manager seeks to maximize the effectiveness of each part of a business, the business strategist seeks to create and arrange these parts into a whole that will succeed in a competitive environment. Business strategists value focus over growth—they must be creative, but also disciplined and not easily distracted.

Business Strategy and Operational Efficiency

A sound business strategy requires several elements (Table 28.1). These include (i) understanding the underlying structure of the industry in which an organization competes; (ii) assessing an organization's strengths, weaknesses, assumptions, and goals, as well as those of its competitors; (iii) identifying a distinctive market position that the organization can occupy more successfully than its rivals; (iv) developing reinforcing business activities that drive the organization toward its desired position in the market; and (v) avoiding common traps that upend the best-laid strategies. These five elements form the basis of this chapter.

Business strategy complements the management of operations, which involves the efficient use of human resources, supply chain management, financial planning, and quality assurance. Managing a clinical laboratory includes a diverse array of responsibilities, including the oversight of testing operations, specimen processing, client services, laboratory safety, information technology, compliance, billing, and marketing. While operational effectiveness and sound business strategy both produce competitive advantage, neither stands on its own. For example, if all laboratory competitors enjoy excellent operational efficiency and produce test results that are equally accurate, inexpensive, and timely, none of the competitors will enjoy a healthy financial return. Competition within the market will drive out profitability and lead to commoditization of laboratory services. Conversely, a laboratory may have a well-developed strategy to serve a defined group of customers that is not being well served by others, but at the same time may lack the operational wherewithal to fully execute

本书版权归John Wiley & Sons Inc.所有

Table 28.1 Elements of strategy

Understanding industry structure
Assessing strengths and weaknesses of your organization and your competition
Identifying a distinctive market position
Adopting business activities that reinforce this market position
Avoiding common strategy traps • Straddling • Growth trap • Profitability trap • Hubris

the strategy and keep its target customers satisfied. It, too, will flounder.

Some may believe that special characteristics of the clinical laboratory industry make it unsuitable for conventional strategic planning. For example, laboratory activities are often concentrated within not-for-profit hospitals, laboratories are subject to a regulatory environment that imposes a high degree of restriction on operational and financial practices, and the strong market power of payors such as Medicare may limit a laboratory's options to find unique market positions. Nevertheless, this chapter will show that clinical laboratories can develop and benefit from a variety of distinctive strategic positions to differentiate themselves from rivals.

Developing and Maintaining a Business Strategy: The Strategic Planning Process

While there is little consensus in the literature about how strategies are best developed, there is growing evidence that strategic planning does in fact have a positive impact on organizational performance (1). Bruce Henderson, founder of the Boston Consulting Group, describes the development of strategy as "an iterative process that begins with a recognition of where you are and what you have now. Your most dangerous competitors are those that are most like you. The differences between you and your competitors are the basis of your advantage" (2). Henderson does not require that all stakeholders in an organization participate in developing a business strategy, or even that it be contained in a written document. He requires only that a business strategy take into account existing differences between an organization and its competitors and purposefully build upon those differences. To Henderson, development of strategy is a creative act.

Development of strategy should be informed and motivated by a broader vision on the direction and potential of an organization. Collins and Porras describe two components of lasting strategic vision as "core ideology" and an "envisioned future" (3). In *Strategy in Action*, Zweifel and Borey further describe the critical importance of strategic vision, specifically to "build a future from the future" while escaping the past (4).

Some downplay the importance of developing a written strategic plan, maintaining that a formal strategic planning process can lead organizations astray. For example, Campbell and Alexander write that the planning frameworks managers use to develop strategy often yield disappointing results because business strategy is about insights and not about plans, which tend to be operational in nature (5). Kim and Mauborgne write that when an inclusive planning process is used to formulate strategy, the competing agendas of an organization's various stakeholders limit development of a clear sense of purpose (6). Others recommend a more formal procedure in which input is solicited from a firm's owners, board of directors, managers, employees, and customers and is incorporated into a written document called a strategic plan. Such a collaborative approach to strategic planning can help to support employee buy-in during subsequent implementation phases (7).

Not-for-profit companies tend to be particularly attracted to a formal, inclusive planning procedure. This may be the result of discomfort that many not-for-profit organizations experience in framing their business in competitive terms. Mission-based organizations also lack some of the direct feedback that for-profit companies obtain from the market, and a formal strategic planning process may substitute for the validation or immediate consequence that for-profit companies may encounter.

A formal strategic planning process consists of several steps (Table 28.2). The process generally begins with a commitment by leadership to identify a strategic direction for the organization. Typically, a planning committee is created to specify important stakeholders and the information that will be collected in the planning process. The second step of the planning process involves development or refinement of a mission statement—what the organization values and seeks to accomplish. The third step involves a situation analysis, in which the strengths and weaknesses of the organization are articulated, along with external threats and opportunities. This generally takes the form of a competitor analysis, a process described later in this chapter. The fourth step of the strategic planning process involves the development of specific objectives and tactics that will further the organization's mission, given the realities that surface during the situation analysis. Finally, the planning committee summarizes the

Table 28.2 The formal strategic planning process

Formation of a strategic planning committee
Development of a mission statement
Situation analysis (strengths, weaknesses, opportunities, threats)
Development of tactics to further the organization's mission
Writing of formal strategic plan

本书版权归John Wiley & Sons Inc.所有

conclusions in a strategic plan, which is given to the board of directors and senior staff to evaluate and put into practice.

Whether or not a formal process is used to develop a business strategy, all strategies are shaped by the underlying structure of the industry in which an organization competes. The general structure of the clinical laboratory industry is therefore described next.

Structure of the Clinical Laboratory Industry

Competition in any field is rooted in economics unique to that industry. Competitive pressure is applied not only from existing rivals but also from potential new entrants, substitute products, customer bargaining power, and supplier bargaining power (8). Together, these are the "Five Competitive Forces" as described by Michael Porter that fundamentally shape strategy (8). The clinical laboratory industry has its own unique underlying structure.

The Testing Market

The clinical laboratory market comprises approximately 3% of overall healthcare expenditures in the United States, and it has been estimated that spending on clinical laboratory services is approximately $100 billion per year (9). The Centers for Medicare and Medicaid Services (CMS) reports that there are approximately 330,000 laboratory facilities operating under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) authority (10). Clinical test activity continues to grow each year due to ongoing changes in clinical practice, the introduction of new tests, and the growth and aging of the U.S. population. Growth in revenue can be the result of increases in test volume, a shift in test mix toward more esoteric testing (e.g., genetics), and it is offset by reductions in payor reimbursements. Overall, approximately 300,000 people work in the clinical laboratory industry in the United States alone (11). This includes a variety of roles, including clinical laboratory professionals, technicians, specimen processors, phlebotomists, couriers, supervisors, managers, pathology assistants, billing and coding professionals, customer services representatives, and laboratory directors to name just a few.

It should be noted that the COVID-19 pandemic dramatically impacted the diagnostic industry landscape, including temporary decreases in non-COVID testing early in the pandemic (12), and significant federal, state, and private resources being directed toward instrumentation and reagents to support testing for the SARS-CoV-2 virus within laboratories, point-of-care (POC) settings, and through at-home testing. Many companies were also formed to provide diagnostic reagents and testing support as part of the larger global pandemic response. The ability of a given laboratory to offer COVID-19 testing capacity has been a differentiator causing many primary care offices and health systems to reevaluate prior laboratory relationships. Many at-home testing options have competed as substitute products for traditional laboratory services, even when served by less-accurate devices (13). Additionally, severe supply shortages have highlighted some of the problems with traditional reagent and supply contracts, which in retrospect have placed too much emphasis on lowering cost and minimizing onsite inventory and not enough on delivery guarantees. It is likely that the pandemic and corresponding resource allocations and constraints will impact the industry in ways that are not yet appreciated.

Concentration of Competitors

The U.S. outpatient clinical laboratory industry is highly fragmented geographically. There are many hospital and outpatient clinical laboratories, but few that operate over large geographic areas. Most outpatient markets are served by one or two large commercial laboratories. The reference testing industry is more concentrated. The six largest laboratories account for nearly half of the reference laboratory testing based on Medicare revenues (9), and mergers have reduced competition in the outpatient and reference laboratory testing market.

Hospital mergers and strategic alliances have also reduced competition among hospital laboratories. More recent trends in the acquisition and/or management of hospital laboratories by commercial reference laboratories are further contributing to consolidation in the industry. The physician office laboratory market is less concentrated than the commercial and hospital-based laboratory markets based on the nature and wide distribution of physician-office locations.

Barriers to Entry

State and federal regulations have traditionally constituted a significant barrier to the entry of new competitors to the clinical laboratory market. Certificate of need laws in many states prevent the construction of new hospitals without regulatory approval. In addition, laws limit the acquisition of not-for-profit hospitals by for-profit companies. Clinical laboratories must also meet regulatory and quality system requirements specified under CLIA regulations and elsewhere (10). Most hospital laboratories meet these requirements by participating in the College of American Pathologists (CAP) Laboratory Accreditation Program (14) or The Joint Commission (TJC) Laboratory Services Accreditation Program (15), both of which have deemed accreditation authority from CMS under CLIA (10). CLIA regulations, for example, specify that laboratory directors and staff must meet certain educational and experience standards.

本书版权归John Wiley & Sons Inc.所有

Because most diagnostic testing requires a physician's order, doctors represent an important distribution channel that must be accessed by any new entrant in the laboratory industry. Most physicians in private practice who participate in managed-care arrangements are accustomed to using several different laboratories for patients enrolled in different health plans. However, physicians employed in staff-model practices or who are affiliated with tightly integrated independent practice associations may not be available to new laboratory entrants and therefore represent a barrier to entry into the testing market. Consolidation of physician practices can also be expected to increase barriers to entry for clinical laboratories.

Switching costs—the cost incurred by a customer switching from one producer to another—also constitutes a barrier to entry. In the reference laboratory market, the significant effort required to configure and test new laboratory-to-laboratory order and result electronic interfaces tends to lock in customers and reduce competitive pressures. Additional factors include the time and resources associated with contractual negotiation, clinical issues such as incorporation of different reference intervals associated with alternative platforms, and adoption of new processes for specimen send-outs and courier pickups. Conversely, limited SARS-CoV-2 test availability early during the COVID-19 pandemic emphasized for many laboratories the importance of having more than one reference laboratory option in case of emergencies. Consideration of alternative providers is also influenced by changes in test volumes or changes in the types of testing requested by providers.

Separation of Payor, Purchasing Agent, and Beneficiary

The U.S. healthcare industry is characterized by an unusual separation of roles that are typically combined in other industries. The beneficiaries of services (patients) do not generally pay for services directly. Most payments for health services are made by government insurance programs (e.g., Medicare and Medicaid) or private insurance companies that are supported by employer contributions. To add to the complexity, neither the payors nor the beneficiaries act as purchasing agents of clinical laboratory services. Physicians and other licensed practitioners order almost all laboratory tests—in many states, it is illegal for patients or insurers to order laboratory tests. Direct access testing (DAT; also known as direct-to-consumer testing) laws—in which consumers are permitted to directly order laboratory tests (16)—are, however, becoming increasingly common across U.S. states and may further impact how testing is conducted and paid for in some use cases. The separation of beneficiaries, payors, and purchasing agents creates a number of market distortions that have been widely studied. Teisberg et al. have reviewed the implications of this separation of roles on competition and incentives in healthcare (17). For example, they note that a conflict of interest exists between many payors and patients, as payors are often incentivized to deny coverage rather than promote innovative solutions that enhance competition and improve quality outcomes (17). Furthermore, copayments can limit a patient's motivation to seek preventive care that could mitigate the need for more expensive services years later.

Economies of Scale

Economies of scale describe the savings in production costs that are typically observed at increased production volumes. Like other industries, analytical operations across laboratories including chemistry, hematology, microbiology, and genetics are also subject to substantial economies of scale. This can be accomplished through decreased costs per unit in high-volume contracts from reagent suppliers, use of high-throughput analytical instrumentation that is not practical and/or affordable in low-volume settings, and preanalytical automation that minimizes manual repetitive tasks and non-value-added labor from overall expense. For routine clinical laboratory tests, payor reimbursement rates tend toward the marginal cost of efficient, high-volume laboratories. Low levels of reimbursement constitute a barrier to new entrants that seek to offer routine clinical testing and reduce margins for the remaining providers. Additionally, lag time between the introduction of methods based on new technologies or new clinical markers and the establishment of formal reimbursement rates further limits the loss of potential revenue.

Restrictions on Markups and Kickbacks

Federal anti-markup rules prohibit physicians and their employers from marking up Medicare and Medicaid charges billed to their practices. Some U.S. states also prohibit physicians from marking up laboratory charges when billing nonfederal insurance programs. Furthermore, anti-kickback laws—e.g., the Anti-Kickback Statute (AKS) and the Eliminating Kickbacks in Recovery Act (EKRA) (18)—prohibit laboratories from providing referring physicians with goods or services of value in exchange for referral of laboratory tests. These restrictions have been enacted to reinforce the duties of physicians to their patients by eliminating financial incentives to order unnecessary tests or to select laboratories based on the physician's potential to profit from the transaction.

Powerful Sellers and Buyers

Powerful sellers of equipment, reagents, supplies, or testing services can also impact the laboratory industry. While large purchasing cooperatives can enable clinical laboratories to impose competitive pressures on the manufacturers of testing equipment and reagents, this is difficult with

本书版权归John Wiley & Sons Inc.所有

sole-source manufacturers, or when a vendor controls the intellectual property of an assay that is in high clinical demand. An example of a powerful seller to the laboratory industry is the American Red Cross, which supplies approximately 40% of blood products to hospitals across the country (19). With testing requirements related to blood safety and challenges in ensuring an adequate supply of blood donors, blood and blood products continue to be a significant expense for many hospital-based laboratories (20).

The laboratory industry also experiences significant pressure from powerful buyers, which the industry refers to as "payors." These include Medicare, Medicaid, and large commercial insurers. These buyers profoundly shape the clinical laboratory industry through imposition of fee schedules that place upper bounds on effective industry pricing, claim edits that place limits on the frequency or clinical setting in which services can be ordered and the manner in which tests can be billed, geographic service requirements or adjustment factors, and turnaround time or result reporting requirements.

Substitute Products

The clinical laboratory industry is beginning to face additional pressure from substitute products in the context of over-the-counter testing products, POC instrumentation used by nonlaboratory providers, and direct-to-consumer marketing. Currently, much of the commonly ordered clinical laboratory testing is categorized as high- or moderate-complexity, and thereby subject to extensive regulation under CLIA. This generally makes it somewhat unsuitable for easy displacement by low-cost, lower-quality over-the-counter products. This situation is changing, however, as manufacturers develop new technologies to create reliable, low-cost, low-complexity analytic test platforms that may be eligible for CLIA-waived approvals.

Unique Economics of Inpatient Care

For most inpatient care, laboratory testing is not a separate reimbursable service but is reimbursed on a per diem basis or on the basis of diagnosis-related groups. As a result, inpatient laboratories are inextricably tethered to the providers of inpatient care in facilities that own and manage their inpatient testing operations. While many hospital-based laboratories also offer outreach testing programs for outpatient services, many follow the strategic direction set by its parent institution and focus primarily on inpatient care testing.

Conclusions

The structural elements of the laboratory industry impose potential boundaries on laboratory business strategies. In many ways, routine inpatient and outpatient physician-ordered clinical laboratory testing is increasingly reflective of a mature market, defined as one where "competition is fast approaching a zero sum game, where one firm's economic gain comes at the expense of another" (21). To develop a unique strategy for a particular laboratory, the strategist must work within these structural constraints or identify new business opportunities. This is most often accomplished by studying the strengths and weaknesses of an organization and its closest competitors.

Competitor Analysis

The objective of competitor analysis is to predict competitors' behavior, both on their own initiative and in response to the actions of rivals. The strategy, position, and capabilities of competitors may limit an organization's opportunities for growth in some areas while simultaneously suggesting other areas in which an organization might expand with little challenge. Conducting an environmental assessment of competition can be an important step for clinical laboratories in strategic planning (22).

Competitor analysis often relies on a procedure referred to as SWOT analysis, an acronym that describes an assessment of an organization's own strengths and weaknesses and external opportunities and threats. This procedure often begins with an inward examination of an organization's capabilities and ends with an outward examination of rivals (Fig. 28.1). Alternatively, Minsky and Aron suggest that external analysis should be conducted first, as factors that influence the market are likely to impact all competitors (23). Through SWOT analysis a strategist may discover opportunities for market expansion or repositioning, or alternatively identify areas in which an organization is vulnerable. Additionally, as noted by Dobbs and Dobbs in *Strategic Planning: A Pragmatic Guide*, the SWOT analysis also helps to create a "common fact base" for leadership which subsequent analysis and strategic planning can work from (24). Examples of SWOT analyses are widely available on the Internet.

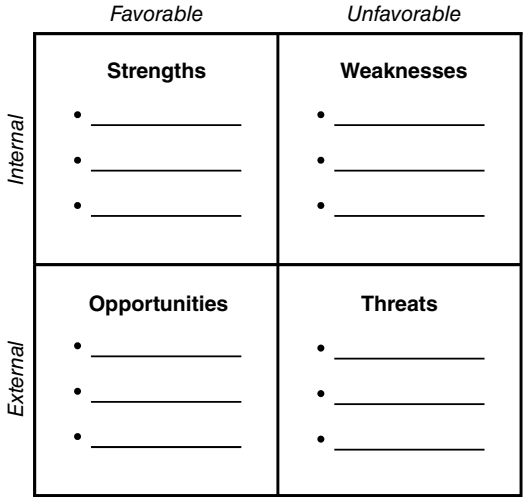


Figure 28.1 SWOT analysis.

本书版权归John Wiley & Sons Inc.所有

In the academic business literature, competitor analysis is a sophisticated process in which the future goals, assumptions, and capabilities of competitors are analyzed with the aim of predicting a competitor's response profile (25). The following assessments are commonly included in a formal competitor analysis.

Competitors' Goals

What are the business objectives of major current and potential competitors? Is a company most interested in generating returns on investment or sales growth? Is short-run or long-run performance most important? What incentive systems are used for management and sales? Does the competitor have non-economic values that form part of its culture and that help determine how it will behave? If the competitor is a business unit of a larger company, how important is the unit to the overall company strategy?

Most hospital-based laboratories are part of not-for-profit hospitals that have a distinctive culture. Emphasis is often placed on fulfilling a non-economic social mission for which laboratory success is tangential. Volume of medical center activity is often expressed in "adjusted discharges"—a unit of activity that reflects the historical importance of inpatient care and the secondary consideration of outpatient and outreach efforts. Many hospitals may not prioritize outpatient laboratory operations that are under attack by competitors, if executive leadership does not appreciate the potential for additional revenue created by investing resources to support such growth. Laboratory leaders should ensure that senior hospital leadership is aware of the significant contribution that outpatient testing may contribute to overall operational margin.

Competitors' Assumptions

Organizations operate with assumptions about their industry and their place within that industry. One laboratory's leader might believe that the laboratory enjoys greater physician loyalty than its rivals. Another laboratory's leader might believe that the testing industry will rapidly integrate genomic testing to the exclusion of more traditional methodologies. These assumptions will govern competitors' behavior. When rivals' assumptions are incorrect, they create business opportunities. A laboratory that overestimates its customer loyalty will be vulnerable to discounts or incentives. A laboratory that overestimates the importance of offering broad geographic access to managed-care plans may lose business in a regional market in which a smaller rival has partnered with a physician group or a group of hospitals.

Competitors' Capabilities

The strengths and weaknesses of an organization determine its ability to meet its goals. A weak rival is unlikely to represent a competitive threat, even if its goals overlap with those of another organization. An assessment of a rival laboratory's strengths and weaknesses includes a study of its testing menu and other services it provides clients, the number and loyalty of physician and institutional customers, marketing capabilities, operational skills (diagnostic speed and accuracy, specimen logistics, and informatics), patents and proprietary research to which the rival has access, cost structure, financial strength (cash flow and access to capital), and organizational strength (reputation, clarity of purpose, management talent, and special structural characteristics that might make it subject to different regulatory pressures).

Interactions of Competitors

In a market operating with what economists call "perfect competition," the number of organizations offering a particular product or service is so large that the actions of one producer do not influence the actions of other producers. However, in the clinical laboratory industry—which has significant barriers to entry and relatively few direct competitors in a given community—the actions of one party are likely to precipitate reactions from rivals. Competitive situations in which actions precipitate reactions are described by game theory, a branch of mathematics pioneered by John von Neumann, Oskar Morgenstern, and John Nash (26). The wise business strategist will consider likely reactions of rivals before making a change in the marketplace. Every move in business has the potential to shift the competitive equilibrium. Armed with an understanding of a rival's goals, attitudes toward risk, and historic behavior, a strategist may be able to predict his or her rivals' responses to moves the organization might make.

Conclusions

An understanding of competitor aspirations and capabilities prepares the strategist to identify the distinctive needs or customer groups that an organization can satisfy better than its competitors. Defining these needs and establishing strategic positions are the subject of the next section.

Strategic Positions in the Clinical Laboratory Industry

What Are Strategic Positions?

The term "strategic position" refers to an organization's commitment to serve many needs of a specific group of customers, or alternatively the specific needs of many customers. This section will describe several types of strategic positions common across industries. This list of strategic positions is not exhaustive and should not discourage the development of creative new positions. In a competitive

本书版权归John Wiley & Sons Inc.所有

environment, the best strategic positions are often those that are not actively being considered by rivals. This concept is inherent to the popular "blue ocean" (uncontested new market) versus "red ocean" (existing crowded market) strategy described by Kim and Mauborgne (27).

Types of Strategic Positions

There is no single all-inclusive taxonomy of strategic positions. Porter has identified several common types of strategic positions that successful organizations may develop (25, 28). Implicit in this discussion is the tenet that a single company cannot be all things to all people. Strategy involves choices and trade-offs.

Variety-based positioning. Companies that offer only a single or narrow scope of service and perform the service exceptionally well (or inexpensively) demonstrate variety-based positioning. For example, the Safelite Group offers essentially only vehicle auto-glass repair. The company has been organized to offer fast service that can even be performed at a customer's home or alternate locations such as the workplace. In the clinical laboratory industry, the National Prion Disease Surveillance Center, which receives support from the CDC, is an example of a laboratory that has developed a narrow, highly specialized scope of service for critical testing that is not easily performed elsewhere.

Needs-based positioning. When groups of customers have different needs, an organization can elect to serve many or all the needs of a defined group. An example would be the wide array of books, educational materials, and teaching tools offered by Scholastic Corporation, exclusively intended for schools, parents, and children and not the entirety of the broader general public. In the clinical laboratory industry, a company with a large menu of forensic and clinical toxicology assays designed to meet a wide assortment of customer requirements in this area is consistent with needs-based positioning.

Access-based positioning. Access-based positions arise when different groups of customers must be accessed in different ways. These differences may be due to geography or differences in the size of the customer pool. An example of a company with an interest in access-based positioning is Starlink, a division of SpaceX. As many rural customers and individuals in developing countries may not have reliable access to high-speed internet, Starlink is currently working to offer global satellite broadband, but intended primarily for customers who do not have access to other competitive services. As a clinical laboratory example, during the COVID-19 pandemic numerous organizations focused on providing mobile testing for the SARS-CoV-2 virus in order to meet testing needs of underserved and rural populations.

Cost-based positioning. Competitors with lower production or supply costs may be able to profit at market prices that leave other providers without earnings. Given its economies of scale, Walmart generally has lower supply costs than its competitors and has lowered industry pricing to a level that allows it to profit while other, typically local, companies may not be able to be competitive within the same geographic market. In the clinical laboratory industry, several large multi-site national commercial reference laboratories have achieved economies of scale that can make price competition difficult for smaller local hospital laboratory facilities.

Product differentiation–based positioning. Some producers, through marketing or other distinctive attributes, convince purchasers that their product is superior to their competitors' and thereby command a premium price. Apple, for example, has achieved this strategy in its marketing of iPhones, iPads, and MacBooks. As a clinical laboratory example, some laboratories that specialize in next-generation sequencing panels for oncology testing could be perceived as marketing to clinicians in a manner consistent with product differentiation-based positioning.

Strategic Positions of Clinical Laboratories

Diagnostic laboratories have sought a number of distinguishable market positions to differentiate themselves from rivals and defend their operations from competition (Table 28.3). Such positions are also fundamentally reflective of the "who, what, how, and why" of an underlying business model, which describes the customer base, value proposition, value chain, and profit mechanism of an organization (29).

Outpatient-centered testing. Several laboratories with national scope have organized themselves to serve the testing needs of physicians practicing in outpatient settings. These companies compete vigorously for exclusive contracts that allow them to become a "one-stop shop" for the office practitioner who treats patients enrolled in a variety of insurance programs. The large size of these companies allows testing costs to remain low and permits

Table 28.3 Sample strategic positions in the laboratory industry

Outpatient-centered testing
Reference-centered testing
Boutique-laboratory (specialty) testing
Hospital-centered testing
Discipline-centered testing
Community-centered (outreach operation) testing
Multi-hospital core laboratory
Cotenancy (joint ownership)
Purchasing and contracting consortia

本书版权归John Wiley & Sons Inc.所有

profitability despite the low payment levels offered by many managed-care organizations. An extensive courier system, collection sites, and a sophisticated billing system that can handle the insurance requirements of different payors reinforce these companies' strategic positions. These companies are also well positioned to offer information technology solutions and interfaces to electronic medical record systems used by practitioners.

Reference-centered testing. A handful of laboratories provide a comprehensive menu of esoteric and/or complex reference testing that smaller hospital-based or regional laboratories cannot economically perform on their own. Successful competitors in this market manage complex shipping logistics, typically by air, and provide electronic interfaces to referring laboratory information systems. Professional client support is provided to the staff of referring laboratories who may be unsure which test option best matches a physician's requirements or how to interpret results once available. This may also include educational material on websites, specialty-specific updates provided to clinicians, inclusion of expanded interpretive comments with results to assist the ordering providers, and/or access to consultative services with laboratory experts. Specialized software can also allow referring institutions to track the status of pending orders. These types of laboratories often focus on helping referring laboratories incorporate best practices regarding test utilization and cost savings for their institutions and clinical services.

Boutique-laboratory testing. Many laboratories, particularly startups with genetic and/or information technology focus, maintain strategic positions around a very small subset of test offerings, often directly marketed to physicians or the public. These organizations—often called "boutique laboratories"—typify variety-based positioning. They frequently offer unique reporting formats desirable to the specific clinical specialties of their customers. They may also have significant intellectual property ownership over the technologies used by their laboratory, which helps to attract venture capital to support initial operations. New specialized testing in these laboratories often has a higher profit margin than routine assays widely available in other clinical laboratory settings.

Hospital-centered testing. Many laboratories have staked out strategic positions serving a hospital's core patient population—inpatients, ambulatory surgery patients, and emergency department patients. These operations are designed to provide rapid turnaround time appropriate to critical care needs. Laboratory representatives often serve on hospital patient care committees and are attuned to the special coordination and communication needs of this demanding environment.

Discipline-centered testing. Specialized clinical laboratories have evolved to meet the particular needs of physicians within one medical specialty or the needs of one type of commercial concern. Dermatopathology laboratories, forensic testing laboratories, urological pathology laboratories, dialysis testing services, and pharmaceutical trial and/or contract research testing facilities provide specialized diagnostic services required by a subset of purchasers.

Community-centered testing. A number of in-hospital testing operations have expanded into the community outpatient (e.g., "outreach") market, serving a defined medical staff that sees patients in hospital and outpatient settings. These laboratories maintain tight connections with local physicians and often allow seamless access to prior test results as patients move through the healthcare continuum. In one variant of this model, a for-profit company providing management expertise and capital may enter into a joint venture with a not-for-profit hospital to provide community testing services. In another model, providers or hospitals may support joint ventures to provide regional laboratory services.

Multi-hospital core laboratory. Many hospital systems have created core laboratories where routine testing from several hospitals is performed in one location. Outpatient testing from each of the participating hospitals, or from a separate combined outreach operation, is also processed within the core laboratory. This strategic position drives large volumes of testing into the core laboratory, lowering costs beyond levels that can be achieved in many other configurations. The large test volume permits the economical introduction of total laboratory automation to handle repetitive testing and pre- and postanalytical tasks. Rapid response laboratories remain in hospitals to serve the urgent testing needs of hospital patients.

Cotenancy. In this model, a group of not-for-profit hospitals, for example, may collectively own esoteric testing services as tenants-in-common. This operation amounts to a shared cost center and provides hospital laboratories with governance control, pricing flexibility, and a cost structure that cannot be acquired from many reference-centered laboratories (30).

Purchasing and contracting consortia. Purchasing and contracting cooperatives have evolved to provide clinical laboratories with more favorable relations with suppliers and payors. Although not performing testing themselves, purchasing consortia allow testing laboratories to obtain favorable pricing on analytical instruments, reagents, and supplies. Contracting consortia allow testing laboratories to compete collectively for managed care contracts that

本书版权归John Wiley & Sons Inc.所有

require a geographic scope of service that individual members may not be able to offer on their own. This type of arrangement has been used, for example, to allow some hospital-owned laboratories to acquire exclusive laboratory contracts for major health maintenance organization insurers (30).

Conclusions

The design of a business strategy is the process of identifying a strategic position for an organization, informed by the underlying structure of the industry and knowledge of an organization and its competitors' capabilities. Clinical laboratories have developed a wide variety of strategic positions to differentiate themselves in the market. It should also be acknowledged that leadership and positioning strategies must also shift in broader economic or societal crises to adapt to new and unanticipated challenges. Critical strategies during challenging times to help sustain an organization include those that will increase revenue, those that will optimize the structure of an organization, and those that will improve how efficiently an organization operates (31). This has never been more evident in the laboratory industry than during the COVID-19 pandemic.

Designing a business strategy is just a beginning, however. Implementation of a chosen strategy is essential for it to have any practical impact. As described by Zweifel and Borey, "Strategy without execution means at best opportunities lost and resources wasted, and at worst forgotten files that gather dust on the shelves of oblivion" (4). Balanced scorecards are one way that a clinical laboratory can assess quantifiable objectives of a strategic plan (32). It is during implementation, however, that strategy can also collide with existing operations and difficult trade-offs must frequently be made. Strategy implementation and common pitfalls are described in the next section.

Implementing the Strategy: Activity Fit

What Is Activity Fit?

The activities of a company with a successful strategy must "fit" with one another and reinforce the overall strategy, and it is the fit of these activities that makes a business model more resistant to competitive pressure. Porter has described three types of fit: "consistency" (i.e., when all activities line up to support the overall value proposition), "reinforcing" (i.e., when different activities increase the value of one another), and "substitution" (i.e., when the success of one activity can eliminate the need for another) (33). A competitor that copies only one of a rival's business activities will not likely be able to emulate the whole. In Porter's view, "fit locks out competitors by creating a chain that is as strong as its strongest link" (28). Milgrom and Roberts have studied successful manufacturers and found that they too use complementary manufacturing and inventory processes to defend market positions (34).

Activity Fit Involves Trade-Offs

A commitment to reinforcing business activities that sustain competitive advantage requires trade-offs. Trade-offs are "a fork in the road... if you take one path, you cannot simultaneously take the other" (33). Many strategic decisions involve trade-offs and may inadvertently benefit or disadvantage one group over another, and it is often difficult to anticipate these trade-offs early in strategic planning or implementation.

Some hospital-based laboratories with outreach operations, for example, focus their activities on a small group of local physicians with whom they maintain close relationships. These laboratories may want to grow this type of business opportunity to maximize revenue, but also risk falling into a profitability trap as discussed in the following section. While expanding visibility of additional available services within the larger clinical facility may benefit these outpatient practices and strengthen overall collaborative relationships with the laboratory, the fit of these other activities may not be suited to other strategic priorities of the health system. For example, additional outpatient appointments in these services might delay procedure availability for inpatients or other existing in-network providers. Leadership in this hypothetical scenario would be faced with a trade-off of competing priorities.

Failure of Strategy

The best-laid strategy may fall short through bad luck or external developments that no strategist could reasonably foresee. Dobbs and Dobbs suggest that three core issues often contribute to decreased effectiveness of planning efforts—executive misalignment, inadequate preparation or readiness for strategic decision making, and poor execution and deployment (24). Other common types of preventable errors are described in the following sections.

Straddling

The term "straddling" describes an attempt to hold several strategic positions at once. This failure to focus has also been called "mission creep" or "stuck in the middle." The business consequences of straddling may be severe. Although many examples of straddling can be readily identified in retrospect after a venture has failed, it should be noted that straddling may not be easy to recognize in its early stages. Conversely, others argue that to be successful it can sometimes be important to maintain "strategic flexibility," sustaining several alternative strategies as one navigates an uncertain future (35). The concept of leveraging existing competencies and current market

本书版权归John Wiley & Sons Inc.所有

position to grow a business is an accepted competitive practice, but where leveraging ends and straddling begins can be difficult to determine.

Growth Trap

An overemphasis on growth can also cause an organization to lose its competitive advantage. The unfocused pursuit of growth causes organizations to add features and services without first considering whether they fit with an existing strategy or set of competencies. Often, new types of customers are pursued when an organization has little distinctive ability to serve the new customers well.

In the testing industry, the occasional community-centered laboratory has attempted to acquire lucrative managed-care or clinical research testing contracts on its own without partnering with other laboratories or systems. These facilities may have little chance of succeeding independently with overwhelming or uncontrollable volumes. A few hospital-centered laboratories have also added expensive forensic or molecular testing operations without acquiring the transportation, client services, billing, and logistics infrastructures that are necessary to support these services. These operations are also at risk of failure. Some authors who study strategy advocate that firms should maximize market penetration where they already have a distinctive presence, rather than "slugging it out in potentially higher growth areas where a company lacks uniqueness" (28).

Profitability Trap

Clayton Christensen has documented the difficulties experienced by some competitors that focused on their most profitable (and typically most demanding) customer segments (36). Successful organizations have a tendency to embrace the value system of profitable customers and seek to add features to products and services that will appeal to this segment. Christensen has documented that these organizations sometimes ignore what appear to be "inferior" technologies that are only attractive to less profitable customer segments. As the inferior technology improves, however, it moves "upstream" in the value chain and becomes attractive to more customers, eventually disrupting entire industries.

Hubris

Because strategic initiatives are a deliberate perturbation of competitive equilibrium, and because strategic discipline requires explicit trade-offs that must permeate an organization, strategy is best championed by confident high-visibility leaders with the ability to persevere amid distractions. Excessive confidence, however, may also undermine disciplined analysis and result in a loss of focus. Accordingly, hubris must be added to the short list of reasons that strategies frequently fail.

SUMMARY

Business strategy is about equipping an organization to thrive in a competitive market. In competitive markets, producers tend to emulate one another until their products and services become indistinguishable. This process of commoditization benefits consumers through lower costs and higher quality but minimizes profits for producers.

Strategy represents a deliberate effort to resist commoditization and maintain an organization's competitive advantage by defending a distinctive position in the market. A successful strategy is a creative approach that is shaped by the particular industry in which an organization operates and the particular competitors it faces in the marketplace.

Business strategy complements but is different from operational efficiency. Both produce competitive advantage. Many authors believe, however, that strategy is more likely to produce sustained competitive advantage than operational effectiveness, because rivals can more easily emulate operational improvements than good business strategy.

Business strategy is informed by an understanding of the structure of the industry in which an organization competes. It is further advanced by a competitor analysis in which the capabilities of individual competitors are examined. An essential element of business strategy is the selection of a strategic position that defines the customers or needs that an organization seeks to serve. Finally, a strategy is maintained by the implementation of interlocking and reinforcing activities that drive the company toward its strategic position and that are collectively difficult to emulate.

There is no consensus about how good strategies originate. Some argue for a defined strategic planning process in which a formal, written strategic plan is developed following input from a variety of stakeholders. Others believe that the creative insight of a small group of individuals is more likely to produce a successful strategy. Thus, ideas about how to best undertake strategic planning are varied and debated, even though the importance of a well-articulated strategy is widely recognized.

Strategies commonly fail because organizations lose their focus and attempt to emulate competitors. This may often be due to straddling—an attempt to assume several strategic positions concurrently—or due to the unbridled pursuit of growth. Failure may also be due to excessive focus on the needs of the most demanding customer segments or to leadership hubris.

In the clinical laboratory industry, a number of distinctive strategic positions are identifiable. These positions allow focused laboratories to maintain a competitive advantage over rivals in a segment of the testing industry the laboratory claims as its own.

本书版权归John Wiley & Sons Inc.所有

KEY POINTS

- Business strategy is about equipping an organization to thrive in a competitive market. Strategy is distinct from the pursuit of organizational efficiency. Both produce competitive advantage, but neither stands on its own.
- Strategy requires that an organization pursue a defined strategic position, focusing on meeting many needs of a particular set of customers or particular needs of many customers.
- The differences between an organization and its rivals are the source of an organization's competitive advantage and the basis of its strategy.
- Strategy requires trade-offs. Organizations are not well served by pursuing several strategic positions concurrently or by adopting capabilities that are not central to maintaining the organization's strategic position.
- An effective strategy is maintained by interlocking business capabilities that reinforce an organization's market position and that are collectively difficult to emulate.

GLOSSARY

Activity fit Interlocking and reinforcing business practices that define and defend a strategic position.

Commoditization The process by which a product provided by one organization becomes indistinguishable from products provided by other organizations.

Competitive advantage Qualities that allow an organization to outperform its rivals consistently.

Competitor analysis Assessment of the capabilities, goals, assumptions, and strategies of competitors, with the aim of predicting competitor behavior.

Economy of scale Reduction in the cost to produce a unit of product when the level of production increases.

Opportunities Areas for which a business could gain additional competitive advantage if pursued.

Straddling The attempt to execute several distinct business strategies or to hold several strategic positions at once.

Strategic planning An organized process for developing a business strategy.

Strategic position Serving a particular set of customers or meeting a defined set of needs, usually in a manner that is unique.

Strategy The quest for sustainable competitive advantage by means of analysis of industry structure and competitors, identification of a strategic position, and adoption of business practices that defend that position.

Strengths Business capabilities that provide a competitive advantage.

Threats External forces that may diminish a company's competitive advantage.

SWOT An abbreviated strategic analysis that is based on assessment of an organization's own strengths and weaknesses and external opportunities and threats.

Weaknesses Aspects of a business that are particularly susceptible to external competitive threat.

REFERENCES

1. **George B, Walker RM, Monster J**. 2019. Does strategic planning improve organizational performance? A meta-analysis. *Public Adm Rev* **79**:810–819.

2. **Henderson BD**. 1989. The origin of strategy. What business owes Darwin and other reflections on competitive dynamics. *Harv Bus Rev* **67**:139–143.

3. **Collins JC, Porras JI**. 1996. Building your company's vision. *Harv Bus Rev* **74**:65–77.

4. **Zweifel TD, Borey EJ**. 2013. *Strategy-In-Action: Marrying Planning, People, and Performance*. iHorizon, Las Vegas, NV.

5. **Campbell A, Alexander M**. 1997. What's wrong with strategy? *Harv Bus Rev* **75**:42–51.

6. **Kim WC, Mauborgne R**. 2002. Charting your company's future. *Harv Bus Rev* **80**: 76–83, 153.

7. **Wright P**. 2020. Strategic planning. *Nurs Manage* **51**:40–47.

8. **Porter ME**. 2008. The five competitive forces that shape strategy. *Harv Bus Rev* **86**: 78–93, 137

9. **Klipp J**. 2021. *U.S. Clinical Laboratory Industry—Forecast and Trends—2020–2022*. Laboratory Economics, Poughkeepsie, NY.

10. **Centers for Medicare & Medicaid Services**. 2023. Clinical Laboratory Improvement Amendments (CLIA). https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA.

11. **Dunham J, Associates**. 2019. *2019 Economic Impact Study of Independent Clinical Laboratories*. ACLA, Washington, DC.

12. **Jackson BR, Genzen JR**. 2021. The lab must go on—clinical laboratory management in a world turned upside down. *Am J Clin Pathol* **155**:4–11.

13. **Pettengill MA, McAdam AJ**. 2020. Can we test our way out of the COVID-19 pandemic? *J Clin Microbiol* **58**:e02225–e02220.

14. **College of American Pathologists**. 2023. Laboratory Accreditation Program. https://www.cap.org/laboratory-improvement/accreditation/laboratory-accreditation-program. Accessed 14 October 2023.

15. **The Joint Commission**. 2023. Laboratory Services Accreditation Program. https://www.jointcommission.org/accreditation-and-certification/health-care-settings/laboratory-services/. Accessed 14 October 2023.

16. **Ramanathan LV, Erdman P, Pessin MS**. 2020. Direct access testing. Does easy consumer access result in a net gain or net loss in improving population health. *Clin Lab News*. 24 March 2020.

17. **Teisberg EO, Porter ME, Brown GB**. 1994. Making competition in health care work. *Harv Bus Rev* **72**:131–141.

本书版权归John Wiley & Sons Inc.所有

18. Mattioli ML, **Gottfried CE**. 2022. Eliminating Kickbacks in Recovery Act (EKRA): 2021 highlights. *Nat Law Rev*. 1 February 2022.

19. American Red Cross. Blood Supply Statistics. https://www.redcrossblood.org/donate-blood/how-to-donate/how-blood-donations-help/blood-needs-blood-supply.html. Accessed 21 May 2022.

20. Valenstein P, **Praestgaard A**, **Lepoff R**. 2001. Six-year trends in productivity and utilization of 73 clinical laboratories: a College of American Pathologists Laboratory Management Index Program study. *Arch Pathol Lab Med* **125**:1153–1161.

21. Lei D, **Slocum JW**. 2014. *Demystifying Your Business Strategy*. Routledge, New York, NY.

22. Inc. Magazine. May 2010. How to conduct competitive research. https://www.inc.com/guides/2010/05/conducting-competitive-research.html. Accessed 21 May 2022.

23. Minsky L, **Aron D**. 2021. Are you doing the SWOT analysis backwards? *Harv Bus Rev*. Digital Article. 23 February 2021. https://hbr.org/2021/02/are-you-doing-the-swot-analysis-backwards. Accessed 21 May 2022.

24. Dobbs JH, **Dobbs JF**. 2016. *Strategic Planning: A Pragmatic Guide*. Independently Published, Las Vegas, NV.

25. Porter ME. 1998. *Competitive Strategy: Techniques for Analyzing Industry and Competitors*. The Free Press, New York, NY.

26. Cassidy J. 2015. The triumph (and failure) of John Nash's game theory. *The New Yorker*. 27 May 2015.

27. Kim WC, **Mauborgne RA**. 2015. *Blue Ocean Strategy, Expanded Edition: How to Create Uncontested Market Space and Make the Competition Irrelevant*. Harvard Business Review Press, Boston, MA.

28. Hamel G. 1996. Strategy as revolution. *Harv Bus Rev* **74**:69–82.

29. Gassmann O, **Frankenberger K**, **Csik M**. 2014. *The Business Model Navigator: 55 Models that Will Revolutionise Your Business*. Pearson, Harlow, UK.

30. Smart J. 2002. Hospitals in Michigan build unique shared lab. *Dark Rep* **Oct. 28 IX**:(15).

31. Lorange P. 2010. *Leading in Turbulent Times: Lessons Learnt and Implications for the Future*. Emerald, Bingley, UK.

32. Alvarez L, **Soler A**, **Guiñón L**, **Mira A**. 2019. A balanced scorecard for assessing a strategic plan in a clinical laboratory. *Biochem Med (Zagreb)* **29**:020601.

33. Magretta J. 2012. *Understanding Michael Porter: The Essential Guide to Competition and Strategy*. Harvard Business Review Press, Boston, MA.

34. Milgrom P, **Roberts J**. 1995. Complementarities and fit: strategies, structure, and organizational changes in manufacturing. *J Account Econ* **19**:178–208.

35. Raynor ME. 2007. *The Strategy Paradox: Why Committing to Success Leads to Failure [And What to Do About It]*. Doubleday, New York, NY.

36. Christensen C. 2011. *The Innovator's Dilemma: The Revolutionary Book That Will Change the Way You Do Business*. Harvard Business Review Press, Cambridge, MA.

本书版权归John Wiley & Sons Inc.所有

29

Introduction

Constraints on Managerial Function

The Cardinal Rules for Optimizing Performance

Get It Right at the Outset • Expect High Performance • Lead by Example • Involve All Members of the Team • Perceived Fairness Is More Important Than Rigid Equality • Maintain Communication in All Directions • Keep Your Eyes and Ears Open • Act Promptly and Decisively When Necessary • When Problems Surface, Involve Laboratory Leaders and Human Resources as Appropriate

Classic Situations That May Interfere with Optimal Performance

The Underperforming Employee • The Overperforming Employee • The Intrusion of Interpersonal Issues • Individual and/or Group Troublemakers • Weakness of the Supervisory Staff

Practical Issues in the Utilization of Human Resources

Skill Mix of Staff • Cross-Training and Rotation • Mix of Employment Arrangements • Coverage of Vacations, Holidays, and Routine Shifts • Use of Overtime or External Contract Labor

SUMMARY

KEY POINTS

GLOSSARY

ACKNOWLEDGMENT

REFERENCES

Human Resource Management in the Laboratory: An Important Component of Financial Management

Fred Westenfeld and Michael R. Lewis

OBJECTIVES

To establish the importance of managing human resources effectively at the individual unit level as well as at the institutional level

To review the constraints on the ability of a manager to lead his or her crew optimally

To review some important tools for getting the most out of employees

To consider some of the classic problems that may face a unit manager

To provide some specific examples of ways that a manager may get the biggest return from the investment in human resources that the institution has made

Your customers will never be any happier than your employees.

John R. DiJulius III

THE TWO MOST IMPORTANT potentially *manageable* expenses of any business enterprise are the costs of labor and materials. The relative importance of these two factors depends on the nature of the organization's business. A highly automated producer of expensive physical products will likely have very high material costs and lower labor costs. In contrast, for a service firm that produces no physical products, the cost of materials may be minimal, but the highly trained, competent workers who are required to run a successful enterprise will probably come at a high cost.

In the laboratory industry, managers are faced with a difficult situation—an information product for which a highly trained workforce must operate expensive equipment and reagents. On the other hand, the fact that both sides of the equation are important means that there are opportunities for savings in two very different areas. In this chapter, we will concentrate on labor costs because they are ones over which a manager can exert considerable direct influence. Although careful negotiation of contracts and searches for alternative suppliers can reduce the expense of materials, these costs are heavily influenced by volume and frequently managed by supply chain management colleagues outside of the laboratory.

Table 29.1 summarizes selected examples of manageable and unmanageable costs. It must be recognized that there are cost components that are beyond a

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch29.

本书版权归John Wiley & Sons Inc.所有

Table 29.1 Manageable and unmanageable cost components

Manageable	Unmanageable
Number of employees	Employee fringe benefits
Skill mix of employees	Legal or institutional limitations on permitted duties of employees
Scheduling and cross-training of employees	Injury, illness, unexpected leaves of absence
Competitive bidding and selection of cost-effective materials	Volume requirements for materials
Direct costs of operation	Indirect costs assessed by institutional management
	Effects of unanticipated events such as pandemics or cyberattacks

manager's control. Examples of such unmanageable components are sickness, unexpected leaves of absence, and deployment of employees in the National Guard. Although these factors cannot be avoided and often cannot be predicted, their consequences can usually be managed within the budget that has been approved. For an organization to be successful in today's rapidly evolving healthcare environment, provisions for such exigencies in the budget process must be made if possible.

Strong leadership at all levels of the organization is essential if costs are to be kept in line with institutional plans and goals. The many theories and practical approaches that are useful for good management have been covered in other sections of this book and in a variety of excellent books on management. In this chapter, we will attempt to address some practical issues that face the manager on the front lines, drawing on our own experiences.

A frontline manager must function within the rules established by the organization, as well as in accordance with pertinent state and federal laws. The first and most important task, therefore, is to become familiar with the human resources (HR) policies and procedures of your organization. Familiarity with basic tenets of employment law (e.g., the Fair Labor Standards Act) is advisable, as is knowing whom to contact in HR when specific questions arise. (Ideally, the manager has an HR business partner with whom to collaborate and consult during normal operations and not only in crisis scenarios.) In addition, it is critical to understand the written and unwritten culture of both the organization as a whole and the smaller unit to which you belong, presumably the laboratory or one of its subunits. Some organizational rules and regulations may be open to interpretation. A manager must understand that using professional judgment in interpretation or application of the rules is part of the job. Understanding the culture of the organization, however, will help you avoid going out on a poorly supported limb.

When starting a new job, it is useful to identify managerial colleagues who appear to have mastered the system. They can serve as invaluable aids until you gain enough experience to become a resource for subsequent neophytes.

Even an experienced manager must maintain regular contact with superiors. There should be a sixth sense about the possibility of trouble, depending on the nature of the problem and of the employees involved. Areas that are controversial, such as repetitive stress injuries, and employees who may be considered difficult or potentially litigious should elicit early rather than late discussions with superiors. When an issue begins to manifest itself, it is essential that both superiors and a colleague in HR be involved. The most valuable manager is the one who takes the initiative in dealing with problems without burdening superiors unnecessarily yet keeps upper-level managers in touch with what is going on.

Constraints on Managerial Function

The first potential constraint on a manager is implied in the introduction to this chapter. If upper-level leaders lack vision, steadfastness, and consistency, or if they are out of touch, it may become extremely difficult or even impossible for frontline managers to do their jobs (1). The higher up in the organization the problem extends, the greater the odds against correcting the problem quickly. The manager in this situation has only two options: to do his or her best with the tools available and/or to look for a position in another organization. This may also be the case when confronted with inadequate administrative support in the finance or HR domains, an inability to employ an appropriately qualified staff, and/or unworkable limits on allocated hours ("head count").

The presence or absence of a unionized workforce can dramatically affect the way a manager interacts with workers. Depending on the quality of labor-management relationships, a unionized workforce is not necessarily a constraint on managerial function, though unionization adds a layer of complexity that may not exist in an organization that has policies and provisions that support staff members and foster a positive working relationship. The challenges are often substantial with or without a union representative, but the rules may be very different in the two situations, and the manager of unionized employees must be cognizant of the specifics of the union contract. The talented manager will be successful in either situation, and the marginal manager will struggle in each.

Finally, there may be significant constraints placed on a manager by the history and culture of the unit, and perhaps by the capabilities of the employees. In this case, however, the appropriate way to view the situation is as a challenge rather than a constraint. Given support from above, a capable manager should be able to recognize and work through difficulties that may detract from optimal function of the unit (Table 29.2).

本书版权归John Wiley & Sons Inc.所有

Table 29.2 Constraints on unit managers

Quality of upper-level management
Adequacy of financial and accounting support
Adequacy of human resources support
Quality of work force available
Quantity of allocated hours
Unionization of workforce (in some instances)
Past practices (culture) of the unit

The Cardinal Rules for Optimizing Performance

Treating employees the way a manager would like to be treated by their manager is a prerequisite for a high-functioning team. The manager should recognize, however, that some employees may have different preferences from the manager's personal preferences. As such, making a deliberate effort to understand and act upon the varying preferences within the team will help employees feel connected to the team and the organization. It is in everyone's best interest if cooperative activity is the order of the day. Creating a strong work environment is an important place to start.

Staff members who feel that they are making strong contributions to the goals of the department will generally be more motivated. It is important that the manager reminds himself or herself daily to act in a manner promoting a positive workplace to the extent that specific circumstances allow. If the manager can promote development of staff self-confidence and self-respect, this will go a long way toward creating an environment of constant learning and improvement (2).

Get It Right at the Outset

A new manager will be presented with a group of employees who were selected by previous incumbents. Unless the workforce is totally ossified, however, there will be turnover. When that happens, the new manager has an opportunity to influence the tone of the laboratory unit. Assessment and reassessment of staffing needs are key: Does this position need to be filled? Should the allocation of tasks between the open position and other positions be modified? How can we best meet this talent need (3)? Technical competence is obviously an important consideration in an individual contributor, and an acceptable level of skill is essential. Based on years of experience, we are convinced that attitude is at least as important. Quoting a well-known leadership expert, Michael Henry Cohen, "Hire for attitude, train for skill" (4). One of the most difficult managerial decisions is to defer hiring the ready applicant if the right candidate is not immediately available, and a constrained labor market with a shortage of qualified candidates may leave a manager feeling as though this is not a viable option. In the long run, however, and if business needs permit, it generally pays to wait. The challenge is to convince coworkers of the need to continue the search. If a mistake is made in a hiring decision, it is critical to recognize and address the problem as soon as possible.

Expect High Performance

If expectations are made clear, it is much harder for anyone to credibly plead ignorance (5). Most people respond to high expectations. If nothing else, expecting less is likely to produce less. Expecting the best may not be easy for the manager. It is entirely too easy to make value judgments about individuals and to expect only those things that are implicit in the assumption. Moving beyond initial assumptions, however, is an early step toward success. Some of the best leaders, colleagues, teachers, and mentors we've known were the most demanding of excellence.

Lead by Example

Employees often adopt the outlook and habits of their manager. If workers are expected to pitch in and work collaboratively to get the work done, they must see their supervisor doing the same thing. Supervisors must "roll up their sleeves" and work in the trenches as needed. It is important to remember, however, that good habits do not come equally easily to everyone. Some will take more encouragement and coaching than others (6).

Involve All Members of the Team

Most work groups consist of individuals with varied backgrounds and talents. It will not be possible for everyone to pitch in on every project or in every way. There should be an opportunity, however, for all to contribute their abilities to help the unit function optimally. The effective manager recognizes employees' strengths and helps them put those strengths to use (7). Adjust roles to capitalize on individuals' strengths and provide recognition for employees doing good work that draws on those strengths. Good managers learn to identify the strengths of their team members, activate those strengths, and help their teams appreciate the value of complementary talents. Employees who feel a part of a team at work are more engaged and are less prone to burnout and its negative consequences (8).

Perceived Fairness Is More Important Than Rigid Equality

It is impossible to interact with each individual in the same way all the time, although every effort should be made to be equitable and as consistent as possible. Circumstances change, and individuals vary in their needs. Judgment is essential when applying rules and regulations to specific situations. The essence of leadership is making everyone feel valued and a part of the process (9).

本书版权归John Wiley & Sons Inc.所有

Maintain Communication in All Directions

It is important that team members feel comfortable talking with each other and to their supervisor without fear of retribution. The best way to prevent rumor and innuendo is to avoid secrets by facilitating open discussion. Most importantly, free interchange of ideas and concerns is the best way to quash the development of cliques, a frequently counterproductive phenomenon. If a topic cannot be discussed because of institutional strategy or employee confidentiality, it may be possible to indicate that while there are constraints, more information will be made available when possible. Managers and supervisors should be seen regularly out in the open, checking in with staff, not hidden away in their offices. The importance and value of being visible to staff cannot be overemphasized. Regular interaction with peers in leadership roles both within and outside the laboratory is likewise vital, as it facilitates situational awareness and development of a network of leadership colleagues to whom one can turn for (and provide) advice and moral support.

Communication should naturally proceed in multiple directions. It is just as essential that the lines of communication upward be free and clear as that lateral and descending channels be protected. Ideally, there will be regular one-on-one meetings in which the manager or supervisor can share current priorities with their leader, have concerns addressed, and be offered support both in addressing tactical issues and in career growth and development matters (10).

Keep Your Eyes and Ears Open

The recommendation to keep your eyes and ears open is a companion to the one above. The best way to detect disconnects in the communication network is to observe and listen closely while going about the normal routine of daily business. Body language is as important as speech in giving the alert manager clues to incipient problems. Physical proximity to the activity hub is key for the manager, as is regularly leaving the office area to interact with staff.

Act Promptly and Decisively When Necessary

The best way to turn a brewing crisis into one that has boiled over the top of the pot is to ignore it. Action need not be manifested by confrontation. On occasion, judicious temporizing may reduce the heat sufficiently to abort the overflow, but unless the underlying problem is addressed, a recurrence is likely.

When Problems Surface, Involve Laboratory Leaders and Human Resources as Appropriate

As discussed above, the art of management includes knowing when to involve superiors in a problem. Alerting upper-level management to a potential difficulty does not necessitate their involvement. In fact, the better the interaction, the more likely a manager will be left alone to solve the problem.

Human resources colleagues can be excellent advisors regarding the handling of problematic situations. Once a potentially serious problem has been identified, it is important to seek the advice and input of your HR colleagues. Other experienced managers and supervisors can also serve as excellent mentors. Where actions such as initiation of a performance improvement plan or termination are possible, countermeasures, including legal challenges, are also possible. Involving experienced colleagues may help mitigate any repercussions.

Table 29.3 provides a summary of cardinal rules of human resource management and potential consequences of breaking them.

Table 29.3 The cardinal rules for optimizing performance, and possible consequences of breaking them

Cardinal rule	Potential consequences
Get it right at the hiring stage	An underperforming employee or a troublemaker who will consume managerial resources
Expect and inspire cooperative behavior	Employees who are not so inclined will not feel constrained to modify behavior
Lead by example	"If gold ruste, what shal iren do?"—Geoffrey Chaucer describing the Parson in *The Canterbury Tales*
Team involvement	A solution that is perceived as imposed may be less readily accepted
Perception of fairness	A decision with unpleasant consequences will be better received if perceived as fair
Open communication	Without communication, problems will arise and proliferate
Eyes and ears open	Brewing problems may boil over if not recognized early
Act promptly and decisively	Matters are likely to deteriorate if not addressed forthrightly
Involve leaders appropriately	Support in a difficult situation will be more problematic if your leader is not aware of the issue or is not prepared to assist with its resolution
Involve institutional human resources	A problem that escalates will be more difficult to manage if your support system is not activated early

Classic Situations That May Interfere with Optimal Performance (Table 29.4)

The Underperforming Employee

The first challenge in dealing with an underperformer is to understand why the employee is not reaching his or her potential. If there is a lack of confidence, counseling and additional training should be directed at boosting self-esteem. Also, technical confidence can be advanced by successfully achieving specialty certification (if available)

本书版权归John Wiley & Sons Inc.所有

Table 29.4 Classic human resources situations

Situation	Necessary action
The underperforming employee	Identify the reason for the failure to reach potential and tailor counseling accordingly
The overperforming employee	Channel energy in productive ways. Watch for the potential consequences of performance at a level above pay grade
Weakness at the top	Same approaches as for front-line staff but with more urgency

and should be considered for those who are interested. Encouraging involvement in a special project such as validation of a new test or new instrumentation may be a useful tack. If the problem is boredom, once again an additional challenge may be useful. Teaching and/or presenting interesting cases, new information, reviews of proficiency testing specimens, technical advances, and meeting summaries are good ways for staff to gain knowledge and confidence in their abilities. If, on the other hand, the employee has tired of the job or was never truly committed, the direction of counseling may be toward an honest and critical evaluation of career opportunities and challenges. In any event, thorough documentation must be kept throughout the period of evaluation. In the event the employee needs to be terminated, detailed and complete performance documentation is mandatory.

The Overperforming Employee

It may seem strange to consider an overperforming employee a problem. In most situations, of course, the response should be to encourage the star to attempt ever greater feats. However, when an employee is capable of work beyond that defined in the job description or is limited to certain job titles based on formal qualifications (degrees and/or licensure), a conundrum arises. Should the employee be limited strictly to the tasks defined in the job description? That course may well result in a bored and frustrated employee who will seek a job that is more challenging. The other option is to allow the employee to advance to the limits of intellectual ability (within regulatory bounds) rather than bureaucratic guidelines. The result may be an employee who is enriched cerebrally by the expanded experience but not monetarily due to the unchanged job title. It is an exceptional individual who does not eventually resent colleagues who do the same tasks, perhaps less well, for significantly higher pay. The decision as to which road to take must be guided by organizational or union rules, regulatory limitations, and by frank and open discussion with the employee. Those discussions should not be one-time-only but should continue to ensure that resentment does not arise.

The Intrusion of Interpersonal Issues

One of the potential causes of friction in the workplace is carryover from previous interactions with a colleague, either on the job or outside. If a manager senses that personal antipathy may be at the root of a problem, or if that information is volunteered, the response should be the same. Behavior in the workplace must be collegial. Past personal experiences must be parked at the door each day. Rarely, the problem may be more remote, the result of a perceived similarity of a coworker to someone with whom the employee has had a previous negative interaction. If minimizing the need for interaction does not solve the problem, coaching and documentation should occur, after which transfer or resignation may be the only alternative for an employee who cannot exert self-control.

Individual and/or Group Troublemakers

A very difficult problem is the employee who stirs up trouble surreptitiously—outside of work, on breaks, or in the hallway. Often the promotion of cliques is the tactic chosen. It is a recalcitrant problem because it is underground, and the fomenter will usually deny such activities. The primary recourse of the manager is to counsel the disruptive employee and deal with the problems that arise. Clear expectations must be delineated, and the importance of teamwork emphasized. If the employee cannot be induced to join the team, an isolation strategy may be adopted. With patience and care, eventually other employees will see what is going on. It is particularly important not to make the troublemaker a martyr, so to the extent possible, the counseling must be done so as not to appear punitive.

A particularly virulent version of the underground troublemaker is the cloned version. A small group of workers (a *cabal*), acting in concert, can make life miserable for colleagues, for leaders, and for those in other roles. If it is possible to separate members of the group, either spatially or temporally, the problem may be alleviated. An attempt should be made to isolate any obvious leaders. Alternatively, it may be possible to introduce a new actor into the play: someone who is equal in stature to the members of the cabal but has a more productive outlook.

Weakness of the Supervisory Staff

Challenges with staff can occur at any level in the organization. It may take considerable effort and persistence to determine that the problem is with a supervisor or manager, rather than with the frontline employees. Keeping an open mind as to where the difficulty lies is important, as the cure is dependent on correct diagnosis of the dysfunction. Failure of a supervisor to demonstrate trust in his or her employees, for example, may manifest as negative employee behaviors reflecting disengagement. Unfortunately, one still encounters scenarios in which a person possessing great technical ability but lacking skills or even interest in management has been promoted into a managerial role; possession of managerial skills, or at least potential to acquire them, must be considered in the hiring

本书版权归John Wiley & Sons Inc.所有

process. Excellent technical skills do not always translate to excellent management performance. Regardless, providing training and tools to recently appointed leaders is critical to building leadership skills and enriching the organization.

Practical Issues in the Utilization of Human Resources

There are several means available to a manager for optimizing the workforce of a unit. The success of these means will depend to a significant extent on the effective use of the management approaches described above (Table 29.5) (11).

Skill Mix of Staff

It is important to examine on a regular basis the skills required for accomplishment of the goals set for the unit. At the very least, the question should be raised each time there is a new vacancy. Soliciting input from your best staff members often yields insight into how to do things better and more efficiently. Hiring incompletely trained or educated workers for complex tests is false economy (although the skill of the individual may be as important, or more important, than the credentials). Conversely, it is not good stewardship to use overqualified individuals. Some simple testing may be assigned to technicians, who, along with laboratory assistants, can perform other support functions, such as maintenance and accessioning of specimens (12). When using staff with lesser credentials in roles that are appropriate and accepted by regulatory agencies, our experience has demonstrated consistently that good supervision is key to being successful.

Cross-Training and Rotation

Some degree of cross-training (or competence in multiple areas) and rotation through multiple areas is necessary in most laboratories to ensure constant coverage with competent workers. The breadth of coverage of an individual worker depends on the depth of experience and knowledge required for the tests. Workers in a small laboratory in a rural hospital may need to perform many simple tests in a variety of scientific disciplines, whereas a technologist working in a large university hospital or reference laboratory is more likely to be responsible for a restricted number of sophisticated procedures. Even in a large unit, cross-training within the unit is important. The important goal is to strike a balance between what is needed to get the work done, the needs and desires of employees, and the ability for each worker to perform enough procedures to maintain proficiency. The extent to which cross-training is practical will vary tremendously among different types and sizes of diagnostic laboratories.

Table 29.5 Practical approaches to optimization

Parameter	Approach
Skill mix	To the greatest extent possible consistent with good practice, utilize less trained individuals for more routine duties
Cross-training and rotation	Give employees the stimulation of multiple tasks or areas, being careful not to stretch them too thin
Mix of employment arrangements	Consider part-time and/or per diem arrangements if costs of maintaining competency and consistency do not exceed benefits of increased scheduling flexibility
Scheduling	Make clear what is needed to do the job. To the extent possible, allow employees to work out the details among themselves
Use of overtime	Within the constraints of the budget, allow overtime if required to get the job done, but always look for other options

Mix of Employment Arrangements

While having a solid core of full-time employees is essential to the continuity of a unit's day-to-day work and for progress toward long-term goals, having a complementary cohort of part-time workers and individuals who can work on a per diem or ad hoc basis can significantly enhance the supervisor's ability to provide appropriate coverage. Including part-time technologists as part of the team can enhance the skill mix and broaden the spectrum of knowledge and experience available to a unit when the number of allocated full-time equivalents is fixed. In a large hospital, some part-time technologists may be cross-trained individuals who split their time between two divisions of the laboratory; care must be taken, though, to ensure that competency in each area is maintained. Provisions must be made to ensure that even those technologists who log relatively few hours not only keep up with changes in routine laboratory operations (as when new procedures are introduced) but also fulfill their regulatory requirements (continuing education, participation in proficiency testing). Managers may reach differing conclusions regarding the desirability of diversifying employment arrangements after considering the potential benefits and associated costs.

Coverage of Vacations, Holidays, and Routine Shifts

In some instances, institutional policies or contractual obligations will determine the rules of coverage for vacations, holidays, and routine shifts. Often, however, the procedure is undefined and will vary with each unit. Consistent with the cardinal rules, a manager might adopt the following policy:

1. Define the minimum staffing requirements for each type of work situation, e.g., weekday, weekend, holiday.
2. Define positions so as to provide the most flexible coverage. When a new position opens, give the existing

本书版权归John Wiley & Sons Inc.所有

workers a chance to review their schedules. If a worker wants to increase or decrease hours or to change the distribution of work among the daily time periods that must be covered, attempt to balance the request with the needs of the department, but make it clear that fulfilling all requests may not be possible. Getting the work accomplished well and efficiently is always the first priority.

3. Entrust development of the schedule to the involved workers, preferably with a single individual as coordinator. That individual may be an assistant manager or senior technologist but should not be the unit manager. It is important that the coordinator have the support of the group as a whole. The manager should have good working knowledge of the schedule and be available as needed to resolve issues.
4. Solicit requests for vacation time well in advance (e.g., 6 to 12 months in advance). Make it clear that it may not be possible to grant everyone his or her first choice. Try to even out assignment of priority vacation times over a period of years. It may be necessary for the group to decide whether they will pitch in and work harder during the vacation months to allow everyone to have desired time off. Getting the work done, without sacrificing quality, must be the first priority for all concerned.
5. Publish the work schedule far enough ahead for people to make plans (minimum of one month, preferably more).
6. When holes appear in the schedule, ask for volunteers to fill in. Encourage switching of shifts or use of part-time or per diem workers, with overtime as a last resort. It should be clear that the possibility of assigning the slot to a non-volunteer lurks in the background, but avoid resorting to that tactic if at all possible.

Use of Overtime or External Contract Labor

The manager should seek to get the needed work done in the most efficient manner with the least expenditure of financial resources necessary. On occasion it may be necessary to use overtime to complete necessary work. When possible, however, an attempt should be made, within the rules of the institution and in compliance with applicable laws, to use other methods, such as increasing the hours of part-time employees. Staff whose work may be completed before the end of the shift should be trained to pitch in and help their colleagues without hesitation, eliminating the "silo effect." In a well-run operation, this occurs automatically, promoting teamwork and reducing overtime.

Excessive reliance on overtime can lead to burnout and employee retention challenges. In a tight labor market such as that which managers have been facing in the setting of the COVID-19 pandemic, external contract labor (ECL) may be an expensive but necessary resource for filling gaps in staffing (13). The cost to the organization of ECL is not limited to the direct financial expenditure; the time and energy required to train ECL can further drain overworked employees, and the inequity in compensation can lead to jealousy and exacerbate retention problems.

SUMMARY

Unit managers can make important contributions to the success of an organization by exerting careful control over manageable components. Although economies can be realized in both materials and labor expenses, the optimization of human resources will present the greatest challenge and the greatest opportunity for a manager. To accomplish this goal there is a series of commonsense rules. The savvy manager must recognize some classic human resources challenges, including overperforming and underperforming employees and individuals who work at cross purposes to the goals of the team. Specific areas in which financial economies may be realized include careful scheduling, cross-training and/or rotation, and judicious utilization of employees with varying backgrounds and skills.

KEY POINTS

- Provide compassionate, interactive leadership so that employees will understand the goals of the unit as well as the challenges and barriers to achieving those goals.
- Involve all employees in the process so that they feel that they are a part of the solutions that you discover jointly.
- Acknowledge the constraints under which the unit operates and accommodate plans accordingly.
- Recognize at an early stage problems in performance that will interfere with achievement of goals, and take appropriate action.
- Identify the practical issues that will allow employees to use their time most efficiently and get the job done with a minimum of disruption.

GLOSSARY

Cabal A group of people working secretly and underhandedly to overthrow a regime. An acronym for a group of ministers chosen by Charles II of England in 1667: Clifford, Arlington, Buckingham (of Three Musketeers fame), Ashley Cooper (later Earl of Shaftesbury), and Lauderdale.

Constraints Factors that limit the flexibility of action.

Cross-training Training individuals to perform more than one task.

External contract labor (ECL) Workers such as medical laboratory scientists (or nurses), sometimes referred to as

本书版权归John Wiley & Sons Inc.所有

"travelers," who provide services under contracts between laboratories (or hospitals) and staffing agencies instead of as employees of the laboratory (or hospital).

Manageable components A parameter over which a manager has control. Scheduling and use of overtime are manageable. Vacation time and work breaks are defined by government or the institution and are thus not manageable (although the number of employees eligible for these benefits may be).

Rotation Movement of team members through the tasks for which they have been trained, often on a regular, sequential basis.

Silo effect The phenomenon of individuals, teams, or departments within an organization failing to communicate and/or collaborate, resulting in inefficiencies and potentially in failure to meet organizational objectives.

Skill mix The variable backgrounds of team members, all of whom will contribute to the operation. The nature of the work will define the required proportion of workers of each background.

ACKNOWLEDGMENT

A significant portion of the original version of this chapter was written by the late Dr. Washington C. Winn, Jr., whose substantial contributions to this book and the medical microbiology world are well remembered.

REFERENCES

1. **Hassan F**. 2011. The frontline advantage. *Harv Bus Rev* **89**:106–114.

2. **Branden N**. 2001. *The Psychology of Self Esteem: A Revolutionary Approach to Self-Understanding that Launched a New Era in Modern Psychology*. Jossey-Bass, San Francisco, CA.

3. **Cappelli P**. 2013. HR for neophytes. *Harv Bus Rev* **91**:25–27.

4. **Cohen MH**. 2011. *Time to Lead*. Creative Health Care Management, Minneapolis, MN.

5. **Schaffer RH**. 1991. Demand better results—and get them. *Harv Bus Rev* **69**:142–149.

6. **Kotter JP**. 2001. What leaders really do. *Harv Bus Rev* **79**:85–98.

7. **Buckingham M**. 2005. What great managers do. *Harv Bus Rev* **83**: 70–79, 148

8. **Morrissey, M.** 2021. Steps to retain lab technicians and technologists. *Med Lab Observ* **August**:32–34.

9. **Van Siclen, C.** 2019. A self-reflection on recruitment and retention. *Med Lab Observ* **August**:48–49.

10. **Rogelberg SG**. 2022. Make the most of your one-on-one meetings. *Harv Bus Rev* **101**:139–143.

11. **Martin BG**. 1985. Cost containment: strategies and responsibilities of the laboratory manager. *Clin Lab Med* **5**:697–707.

12. **Snyder JR.** Technician or technologist? Sorting out overlapping roles in the lab. *Med Lab Observ* **June**:36–41.

13. **Anonymous**. 2022. Labs hunt for solutions to staffing, plastics, and blood supply shortages. *CAP TODAY*. **January**:1, 22–26.

本书版权归John Wiley & Sons Inc.所有

30

Introduction
Cost Accounting
Classification of Costs • Behavior of Costs • Measuring Full Cost • Average versus Marginal Costs • Actual Cost versus Standard Cost • Costing Issues • A Formula for Developing Laboratory Costs • Laboratory Costing Examples
Break-Even Analysis
Equipment Purchase • Capitation Contract
Capital Acquisition Concepts
Time Value of Money • Depreciation
Budgeting
Types of Budgets • The Budgeting Process • Budget Examples
Variance Analysis
Financial Statements
Financial Ratios
Applications of Financial Tools in the Evolving Laboratory Landscape
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES

Costs, Budgeting, and Financial Decision Making

Geoffrey C. Tolzmann, Richard J. Vincent, and Michael R. Lewis

OBJECTIVES

To learn the types and behaviors of costs, how to measure them, what data are needed to generate a cost analysis, and how to cost a basic laboratory test

To understand the relationships among cost, volume, and profits and calculate contribution margin and break-even point

To apply time-value-of-money concepts to capital acquisition plans using net present value

To understand the three common types of budgets, the budgeting process, and how budgets are used to measure financial performance and to control costs

To be able to analyze the causes of differences in actual financial performance from budgeted amounts and understand how this information is used for management control

To learn about the three primary financial statements: the balance sheet, the income statement, and the cash flow statement

To learn how to calculate key financial ratios that reveal information about an organization's financial health

> *Accounting is the most useful "information system" for managers, because it organizes and accumulates related information over time and aligns it with initial objectives and requirements, called "budgets." Principles of accounting must be applied to other types of information managers use in order to make "information technology" useful.*
>
> Peter F. Drucker, at the Forbes CEO Forum "Management in the 21st Century," June 1997

Too often the financial aspects of the laboratory business can intimidate managers who have a scientific background. However, managers must understand and participate in cost accounting and budgeting. In addition, they must understand the principles of financial accounting and financial analysis in order to gauge performance, because "what gets measured gets managed." This chapter will provide an overview of these extensive and complex activities (1–6).

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch30.

A note on conventions in accounting reporting:

- Variances that are "favorable" are depicted without modification. A favorable variance is an expense that is less than budgeted, or revenue that is greater than budgeted.
- Variances that are "unfavorable" are depicted in parentheses. An unfavorable variance is an expense that is greater than budgeted or revenue that is less than budgeted.
- Profit is depicted in unmodified format and in black ink; loss is depicted in parentheses and in red if a color document is employed.
- "Productive" labor is labor that actually produces a product directly (be it a physical product or an intellectual one).
- "Nonproductive" labor may be necessary for proper functioning of the organization but is not *directly* involved in production of the product. Vacation, conferences, sick time, all management functions, and support activities such as financial analysis and marketing are examples of nonproductive labor. Note that "nonproductive" is not a pejorative term in accounting lingo.

Cost Accounting

Cost accounting is a system of measuring and reporting information about costs. Its purpose is to generate information sufficient for managers to make intelligent decisions. A common challenge of cost accounting systems is balancing the degree of specificity needed with the amount of work required to reach that specificity in light of the decisions to be made. A good system does not require unnecessarily detailed information.

Cost accounting is useful for several purposes:

- *Profitability analysis*. Cost accounting enables managers to determine whether a laboratory division or a market segment is generating revenues in excess of expenses.
- *Cost control*. Cost accounting helps define the relationship between cost and activity and can help align responsibilities with incurred costs.
- *Planning*. Cost accounting helps us understand what happens to costs as activity changes.
- *Decision making*. Cost accounting aids in setting prices, negotiating reimbursement or capitation rates, and making staffing decisions and make-versus-buy decisions (for example, whether to perform a laboratory test in-house or send it to a reference laboratory).

Classification of Costs

Costs can be categorized in many different ways, but the most critical distinction is direct cost versus indirect cost. Direct costs are those costs clearly associated with the item being costed (be it a patient, a service, a department, or an individual assay). In the laboratory, direct costs include testing supplies and reagents, instrument depreciation, maintenance and repairs, and the labor involved in performing testing. Indirect costs are those costs that are not directly associated with the item being costed. The most common types of indirect costs are general laboratory supplies; labor costs associated with supervision, administration, and training; and hospital overhead. The full, or total, cost of an item includes its direct costs and an allocated portion of indirect expenses.

Behavior of Costs

Costs behave in four basic ways depending on their relationship to the relevant range of activity. Variable costs vary in direct proportion to the volume or level of activity, such as reagent cost. Therefore, variable costs are constant per unit of service (UOS), which is whatever the logical measure of work for a given area is. Fixed costs, such as rent, are constant regardless of changes in levels of activity. Therefore, fixed costs per UOS change with volume. Semivariable costs have a fixed and a variable cost component. An example is telephone service, for which customers are usually charged a fixed amount per month that may include a specified amount of service above which a per-unit charge is incurred. Step-fixed costs are fixed over a relatively small range of activity and then change to a new fixed level over another relatively small range of activity. Labor costs often exhibit step-fixed behavior, as a certain staffing level supports a range of activity beyond which additional staffing must be added. The behaviors of most costs are fairly intuitive. Figure 30.1 illustrates these behaviors.

Measuring Full Cost

There are four steps to the process of measuring full costs:

1. Identify the responsibility centers into which costs may be appropriately grouped. For a hospital, these areas might be laboratory, radiology, laundry, etc. Within the laboratory, these centers might be chemistry, hematology, microbiology, central receiving, etc. Within chemistry, the centers might be individual analyzers or testing modalities.
2. Trace all revenues and expenses to the responsibility center incurring them.
3. Allocate the costs of supporting responsibility centers to the revenue-producing centers. There are several techniques by which this allocation may be accomplished:
   - Direct allocation
   - Step-down allocation (which usually entails starting with allocating the costs of centers that provide the

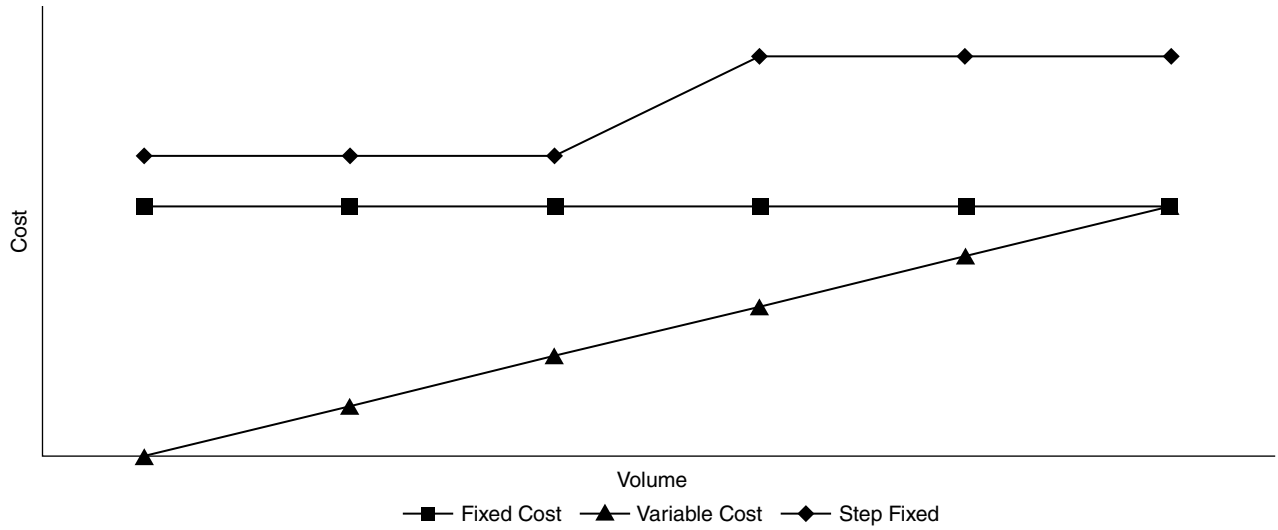


Figure 30.1 Cost behavior.

most services to all other centers, then allocating the costs of those that provide the next level of service, including those costs that were just allocated in the first round, to all others, etc.)

- Algebraic allocation (used by sophisticated cost accounting systems)

  Allocation also requires some sort of basis, such as cause and effect, or facilities provided or ability to bear the allocated costs. Examples of bases include square footage, utilization, visits, number of personnel, revenues, and payroll expense.

4. Determine the average cost of each procedure or service by dividing the responsibility center's costs by the measure of activity (in the laboratory, the measure is usually the number of procedures or billed tests). The average cost per procedure for the laboratory center might be $10, while the average cost per procedure for the chemistry center might be $5, and the average cost per procedure for a specific analyzer center within chemistry might be $2.

Average versus Marginal Costs

As noted above, the average cost equals the full costs divided by the UOS. Marginal cost equals the change in total cost relative to the change in volume. It is the variable cost plus any additional fixed costs incurred because the volume change exceeds the relevant range. In most instances, there are no additional fixed costs. Marginal costs are also called incremental costs. Over the long run, average revenues must be greater than or equal to average costs for an organization to survive, but in the short run, decisions should be made based on marginal costs. For example, the incremental cost of adding another sample to a chemistry analyzer that is running below capacity is very low. If adding another sample requires the purchase of another analyzer, however, its incremental cost is very high.

Actual Cost versus Standard Cost

Standard costs represent what a given item should cost under normal circumstances. Standard costs are useful for comparison to actual cost experience when analyzing cost variances and for budgeting.

Costing Issues

When performing cost accounting, it is always worthwhile to examine the results and ask, Is it fair? Is it equitable? Is it understandable? Do the benefits justify the effort required to ascertain cost?

A Formula for Developing Laboratory Costs

Direct costs of test (instrument depreciation, maintenance and repair, reagents, calibration, quality controls, direct labor)

+

Indirect costs (general laboratory supplies), indirect labor (such as supervision, training), other indirects (such as research and development expenses)

=

Laboratory section cost

+

General laboratory overhead (specimen collection, report distribution, information systems, management, education, quality assurance, sales, marketing)

=

Laboratory test total cost

Laboratory Costing Examples

Tables 30.1 through 30.6 are examples of the types of information that need to be collected and some of the calculations involved in generating unit costs. The data in these and subsequent tables are presented for illustrative purposes and are not intended to be specific to particular years; however, Current Procedural Terminology (CPT) codes have been validated against the 2023 Centers for Medicare and Medicaid Services (CMS) Clinical Diagnostic Laboratory Fee Schedule (7). Table 30.1 shows the key variables that are needed to generate unit cost, including staff costs that are both variable (tester) and fixed (nontester), plus indirect fixed divisional, overall laboratory, and overall hospital costs.

Table 30.1 Key variables for a hematology laboratory with static volume

Position	Type	Average Salary	FTEs	Total Salary Exp	Fringe Expense	Total Salary & Fringe
Lab Specialist	Tester	$ 32,000	1.00	$ 32,000	$ 8,000	$ 40,000
Medical Laboratory Scientist	Tester	$ 40,000	3.00	$ 120,000	$ 30,000	$ 150,000
Medical Lab Technician	Tester	$ 33,500	1.00	$ 33,500	$ 8,375	$ 41,875
Laboratory Supervisor	Non-Tester	$ 47,500	1.00	$ 47,500	$ 11,875	$ 59,375
Total			6.00	$ 233,000	$ 58,250	$ 291,250
Avg Tester Salary & Fringe Benefit Expense						**$ 46,375**
Total Non-Tester Salary & Fringe Benefit Expense						**$ 59,375**

Divisional Indirect Costs	Amount	Cost/Test[a]
Non-Tester Salary & Fringe	$ 59,375	
Office Supplies	$ 10,000	
Books/Subs/Dues	$ 15,000	
Travel Meeting Dues	$ 15,000	
Total	$ 99,375	$ 0.76

Lab Indirect Costs	Amount	
Management	$ 115,000	
Central Receiving	$ 625,000	
General Support	$ 100,000	
Administrative Support	$ 75,000	
Subtotal	$ 915,000	
Hematology % of Total Lab Volume	15%	
Hematology Allocation	$ 137,250	$ 1.04

Hospital Indirect Costs (Lab Portion)	Amount	
Patient Financial Services	$ 500,000	
Human Resources	$ 300,000	
Management	$ 100,000	
Finance	$ 100,000	
Subtotal	$ 1,000,000	
Hematology % of Total Lab Vol	15%	
Hematology Allocation	$ 150,000	$ 1.14

[a] Total volume is 131,469 tests, as shown in Table 30.3.

Table 30.2 is an example of the calculation involved in generating a per-unit cost for a test that is run in a batch with other tests. It is an example of a step-fixed cost. Should the threshold of 250 tests per run be exceeded, another run would need to be instituted, along with its concomitant expenses. The "step" is the period jump in costs with each new test run, whereas the cost per test progressively decreases within each test run as more samples are added. The most efficient position would be the inclusion of 250 tests in *every* run, the situation in which no further savings could be achieved without increasing the capacity of the run. In Table 30.2, the average number of tests per run is 228, a point that approaches the most economic efficiency possible.

Table 30.3 combines all the costing information thus far to calculate a unit cost for a given volume. After generating this cost information, it is important to validate the model by running a check on the total cost captured by the model. This total is measured by multiplying the unit costs by the volume over a given period of time and comparing that to actual costs for the same time period, which were generated in Table 30.1.

Tables 30.4 through 30.6 are the same as the previous examples, except they show the effects of adding an additional 7,500 partial thromboplastin time tests to the mix. Clearly, the additional tests make all the indirect fixed costs less expensive because the same fixed costs are now being divided over a larger number of tests. This relationship is important when generating pricing proposals for new business.

Comparing Table 30.5 with Table 30.2 shows the effects of adding additional tests to the cost of a test run. In Table 30.2 we were able to run the batch of tests five times a week and still be under the test run maximum of 250. With the addition of 7,500 tests, one can see in Table 30.5 that the batch now needs to be run six times a week, which adds more cost and increases the per-unit cost of the tests. Thus, the cost for these tests was fixed within a certain volume level (250 tests per batch), but when the volume went over that level, the costs shifted upward, an example of a step-fixed cost.

Break-Even Analysis

Contribution margin is the revenue per UOS less the marginal cost per UOS, and is often written as contribution margin = price – variable costs. As long as the contribution margin is positive, the organization benefits. The margin can go to supporting fixed costs (or to supporting items or activities whose contribution margin is negative), and if fixed costs have been covered, it represents profit.

The break-even point is the volume of activity required for all fixed costs to be covered. Therefore, the break-even point equals the total fixed cost divided by the contribution margin.

$$\text{Volume break-even point} = \frac{\text{total fixed costs}}{\text{contribution margin per unit}} = \frac{\text{total fixed costs}}{\text{price-variable costs}}$$

This equation underscores the relationships among costs, volume, and profits. In the previous section, we discussed cost behavior and displayed the relationships of fixed and variable costs to volume. A given responsibility center incurs both fixed and variable costs, and its total costs are the sum of the two, as illustrated in Fig. 30.2. Adding the revenue line, which increases at a rate equal to the revenue per unit, yields Fig. 30.3.

If the revenue per unit is greater than the variable cost per unit, the revenue line and the total cost line must cross at some point, where revenues equal costs—the break-even point. Note that the graph illustrates not only the break-even volume, but also the unit revenue required to reach break-even. Figure 30.4 shows this calculation for a hypothetical hematology division.

Equipment Purchase

When considering expensive equipment purchases, it is critical to know the point at which the volume of procedures performed on the equipment covers its annual depreciation and maintenance costs, compared to the projected demand for the procedures, as illustrated in Fig. 30.5.

Capitation Contract

Under "capitation," healthcare providers are paid a fixed amount per member per month (PMPM). Revenue varies, therefore, with member enrollment, not with the volume of procedures performed. To understand what the break-even point is in terms of the number of members, a provider must first understand the expected utilization by those members (see Fig. 30.6). The provider, not the health plan, is usually at risk for variations in utilization. This risk can be ameliorated by negotiating utilization corridors into the contract, whereby the PMPM revenue is adjusted up or down if utilization is over or under budget by a certain amount. If not, the provider can incur significant losses if utilization is over budget.

Capital Acquisition Concepts

Time Value of Money

Before evaluating potential capital acquisitions, it is important to understand the concept of the time value of money. Most people prefer current consumption to future consumption. Similarly, investors expect to be rewarded for their patience by receiving a rate of return on an investment, which could be interest, dividends, or capital gains. Intrinsic in this is the notion that money received in the future is not as valuable as money received today. We can quantify this. The future value (FV) of an investment = its present value (PV) multiplied by (1 + interest rate, k) raised to the number of investment periods, n (usually expressed as years), or

$$\text{FV} = \text{PV} \times (1 + k)^n$$

Table 30.2 Test run calculation for a hematology laboratory with static volume[a]

Division	Test Description	CPT Code	Total Volume	Test Run Volume	Current Runs/Week	Maximum Tests/Run	Avg Tests per Run	Test Run Minutes	Total Year Salary & Fringe Expense	Total Year Supplies & Reagent Expense	Salary & Fringe Expense per Test	Supplies & Reagents Expense per Test
	Thromboplastin time partial	85730	25,973									
	Prothrombin time	85610	33,318									
HEMATOLOGY	HEMA001 Test Run			59,291	5	250	228	180	$ 17,391	$ 5,200	$ 0.29	$ 0.09

[a] CPT codes in this and subsequent tables have been validated against the 2023 CMS Clinical Diagnostic Laboratory Fee Schedule (7).

Table 30.3 Cost calculation for a hematology laboratory with static volume

						DIRECT COST					INDIRECT COST					
						Variable Cost			Step-Fixed Cost		Fixed Cost					
Division	Test Description	CPT Code	Total Volume	Additional Volume	Revised Volume	Test Minutes	Test Salary & Fringe	Test Supplies & Reagents	Test Run Sal & Frg	Test Run Supp & Reag	Divisional Cost	Lab Cost	Hospital Cost	Variable Cost	Fixed Cost	Total Cost
HEMATOLOGY	Fibrinogen activity	85384	2,057	–	2,057	5	$ 1.86	$ 1.00	$ –	$ –	$ 0.76	$ 1.04	$ 1.14	$ 2.86	$ 2.94	$ 5.80
HEMATOLOGY	Heinz bodies direct	85441	10	–	10	5	$ 1.86	$ 1.00	$ –	$ –	$ 0.76	$ 1.04	$ 1.14	$ 2.86	$ 2.94	$ 5.80
HEMATOLOGY	Spun microhematocrit	85013	107	–	107	5	$ 1.86	$ 1.00	$ –	$ –	$ 0.76	$ 1.04	$ 1.14	$ 2.86	$ 2.94	$ 5.80
HEMATOLOGY	Hemoglobin fetal	85460	342	–	342	3	$ 1.11	$ 0.50	$ –	$ –	$ 0.76	$ 1.04	$ 1.14	$ 1.61	$ 2.94	$ 4.56
HEMATOLOGY	WBC alkaline phosphatase	85540	29	–	29	3	$ 1.11	$ 0.50	$ –	$ –	$ 0.76	$ 1.04	$ 1.14	$ 1.61	$ 2.94	$ 4.56
HEMATOLOGY	Russell viper venom diluted	85613	133	–	133	3	$ 1.11	$ 0.50	$ –	$ –	$ 0.76	$ 1.04	$ 1.14	$ 1.61	$ 2.94	$ 4.56
HEMATOLOGY	Complete CBC automated	85027	63,600	–	63,600	5	$ 1.86	$ 0.50	$ –	$ –	$ 0.76	$ 1.04	$ 1.14	$ 2.36	$ 2.94	$ 5.30
HEMATOLOGY	Thromboplastin time partial	85730	25,973	–	25,973	–	$ –	$ –	$ 0.29	$ 0.09	$ 0.76	$ 1.04	$ 1.14	$ –	$ 3.32	$ 3.32
HEMATOLOGY	Blood platelet aggregation	85576	17	–	17	10	$ 3.72	$ 2.00	$ –	$ –	$ 0.76	$ 1.04	$ 1.14	$ 5.72	$ 2.94	$ 8.66
HEMATOLOGY	Prothrombin time	85610	33,318	–	33,318	–	$ –	$ –	$ 0.29	$ 0.09	$ 0.76	$ 1.04	$ 1.14	$ –	$ 3.32	$ 3.32
HEMATOLOGY	Clot inhibit prot C activity	85303	181	–	181	10	$ 3.72	$ 2.00	$ –	$ –	$ 0.76	$ 1.04	$ 1.14	$ 5.72	$ 2.94	$ 8.66
HEMATOLOGY	Clot inhibit prot S free	85306	175	–	175	10	$ 3.72	$ 2.00	$ –	$ –	$ 0.76	$ 1.04	$ 1.14	$ 5.72	$ 2.94	$ 8.66
HEMATOLOGY	RBC sed rate automated	85652	5,527	–	5,527	15	$ 5.57	$ 4.00	$ –	$ –	$ 0.76	$ 1.04	$ 1.14	$ 9.57	$ 2.94	$ 12.51
	Total		131,469	–	131,469											
	Cost Capture Check															
	Total Calculated Cost		$ 621,257													
	Total Actual Cost		$ 677,875													
	Cost Capture Percent		91.6%													

Table 30.4 Key variables for a hematology laboratory with additional volume

Position	Type	Average Salary	FTEs	Total Salary Exp	Fringe Expense	Total Salary & Fringe
Lab Specialist	Tester	$ 32,000	1.00	$ 32,000	$ 8,000	$ 40,000
Medical Laboratory Scientist	Tester	$ 40,000	3.00	$ 120,000	$ 30,000	$ 150,000
Medical Lab Technician	Tester	$ 33,500	1.00	$ 33,500	$ 8,375	$ 41,875
Laboratory Supervisor	Non-Tester	$ 47,500	1.00	$ 47,500	$ 11,875	$ 59,375
Total			6.00	$ 233,000	$ 58,250	$ 291,250
Avg Tester Salary & Fringe Benefit Expense						**$ 46,375**
Total Non-Tester Salary & Fringe Benefit Expense						**$ 59,375**

Divisional Indirect Costs	Amount	Cost/Test[a]
Non-Tester Salary & Fringe	$ 59,375	
Office Supplies	$ 10,000	
Books/Subs/Dues	$ 15,000	
Travel Meeting Dues	$ 15,000	
Total	$ 99,375	$ 0.72

Lab Indirect Costs	Amount	
Management	$ 115,000	
Central Receiving	$ 625,000	
General Support	$ 100,000	
Administrative Support	$ 75,000	
Subtotal	$ 915,000	
Hematology % of Total Lab Volume	15%	
Hematology Allocation	$ 137,250	$ 0.99

Hospital Indirect Costs (Lab Portion)	Amount	
Patient Financial Services	$ 500,000	
Human Resources	$ 300,000	
Management	$ 100,000	
Finance	$ 100,000	
Subtotal	$ 1,000,000	
Hematology % of Total Lab Vol	15%	
Hematology Allocation	$ 150,000	$ 1.08

[a] Revised volume is 138,969 tests, as shown in Table 30.6.

The future value in 3 years of $100 invested at 5% interest equals $\$100 \times (1 + 0.05)^3 = \$115.76$. This formula becomes useful in considering capital acquisitions when we rearrange the terms:

$$PV = \frac{FV}{(1+k)^n}$$

Here, the rate k is called the discount rate (not the interest rate), and the practice is called discounting (we are discounting the value of money, not to be confused with discounting, or reducing the price of, a test charge). This approach allows us to value different investments in today's dollars in relation to their future values. Which would you rather receive: $115.76 in 3 years or $120.34 in 4 years? At a

Table 30.5 Test run calculation for a hematology laboratory with additional volume

Division	Test Description	CPT Code	Total Volume	Test Run Volume	Current Runs/Week	Maximum Tests/Run	Avg Tests per Run	Test Run Minutes	Total Year Salary & Fringe Expense	Total Year Supplies & Reagent Expense	Salary & Fringe Expense per Test	Supplies & Reagents Expense per Test
	Thromboplastin time partial	85730	33,473									
	Prothrombin time	85610	33,318									
HEMATOLOGY	HEMA001 Test Run			66,791	6	250	214	180	$ 20,869	$ 6,240	$ 0.31	$ 0.09

Table 30.6 Cost calculation for a hematology laboratory with additional volume

						DIRECT COST					INDIRECT COST					
						Variable Cost			Step-Fixed Cost		Fixed Cost					
Division	Test Description	CPT Code	Total Volume	Additional Volume	Revised Volume	Test Minutes	Test Salary & Fringe	Test Supplies & Reagents	Test Run Sal & FCrg	Test Run Supp & Reag	Divisional Cost	Lab Cost	Hospital Cost	Variable Cost	Fixed Cost	Total Cost
HEMATOLOGY	Fibrinogen activity	85384	2,057	–	2,057	5	$ 1.86	$ 1.00	$ –	$ –	$ 0.72	$ 0.99	$ 1.08	$ 2.86	$ 2.78	$ 5.64
HEMATOLOGY	Heinz bodies direct	85441	10	–	10	5	$ 1.86	$ 1.00	$ –	$ –	$ 0.72	$ 0.99	$ 1.08	$ 2.86	$ 2.78	$ 5.64
HEMATOLOGY	Spun microhematocrit	85013	107	–	107	5	$ 1.86	$ 1.00	$ –	$ –	$ 0.72	$ 0.99	$ 1.08	$ 2.86	$ 2.78	$ 5.64
HEMATOLOGY	Hemoglobin fetal	85460	–	–	342	3	$ 1.11	$ 0.50	$ –	$ –	$ 0.72	$ 0.99	$ 1.08	$ 1.61	$ 2.78	$ 4.40
HEMATOLOGY	WBC alkaline phosphatase	85540	29	–	29	3	$ 1.11	$ 0.50	$ –	$ –	$ 0.72	$ 0.99	$ 1.08	$ 1.61	$ 2.78	$ 4.40
HEMATOLOGY	Russell viper venom diluted	85613	133	–	133	3	$ 1.11	$ 0.50	$ –	$ –	$ 0.72	$ 0.99	$ 1.08	$ 1.61	$ 2.78	$ 4.40
HEMATOLOGY	Complete CBC automated	85027	63,600	–	63,600	5	$ 1.86	$ 0.50	$ –	$ –	$ 0.72	$ 0.99	$ 1.08	$ 2.36	$ 2.78	$ 5.14
HEMATOLOGY	Thromboplastin time partial	85730	25,973	7,500	33,473	–	$ –	$ –	$ 0.31	$ 0.09	$ 0.72	$ 0.99	$ 1.08	$ –	$ 3.19	$ 3.19
HEMATOLOGY	Blood platelet aggregation	85576	17	–	17	10	$ 3.72	$ 2.00	$ –	$ –	$ 0.72	$ 0.99	$ 1.08	$ 5.72	$ 2.78	$ 8.50
HEMATOLOGY	Prothrombin time	85610	33,318	–	33,318	–	$ –	$ –	$ 0.31	$ 0.09	$ 0.72	$ 0.99	$ 1.08	$ –	$ 3.19	$ 3.19
HEMATOLOGY	Clot inhibit prot C activity	85303	181	–	181	10	$ 3.72	$ 2.00	$ –	$ –	$ 0.72	$ 0.99	$ 1.08	$ 5.72	$ 2.78	$ 8.50
HEMATOLOGY	Clot inhibit prot S free	85306	175	–	175	10	$ 3.72	$ 2.00	$ –	$ –	$ 0.72	$ 0.99	$ 1.08	$ 5.72	$ 2.78	$ 8.50
HEMATOLOGY	RBC sed rate automated	85652	5,527	–	5,527	15	$ 5.57	$ 4.00	$ –	$ –	$ 0.72	$ 0.99	$ 1.08	$ 9.57	$ 2.78	$ 12.36
	Total		131,469	7,500	138,969											
	Cost Capture Check															
	Total Calculated Cost		$ 625,775													
	Total Actual Cost		$ 677,875													
	Cost Capture Percent		92.3%													

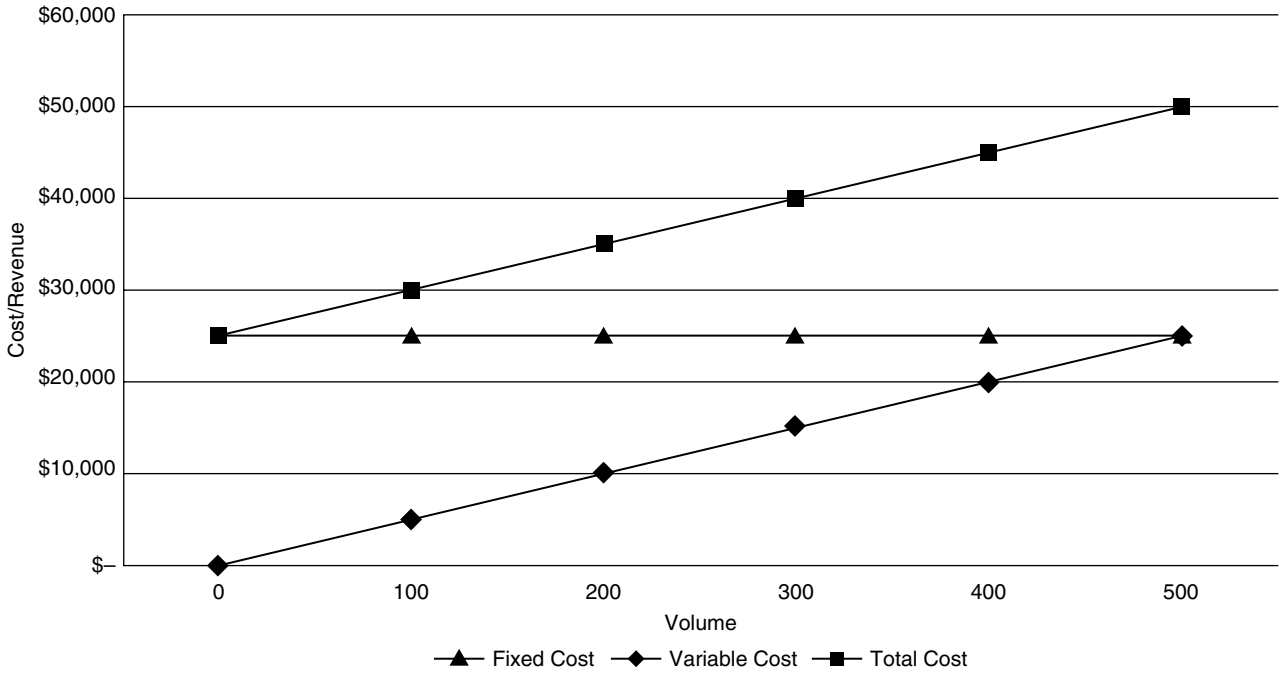


Figure 30.2 Fixed, variable, and total cost.

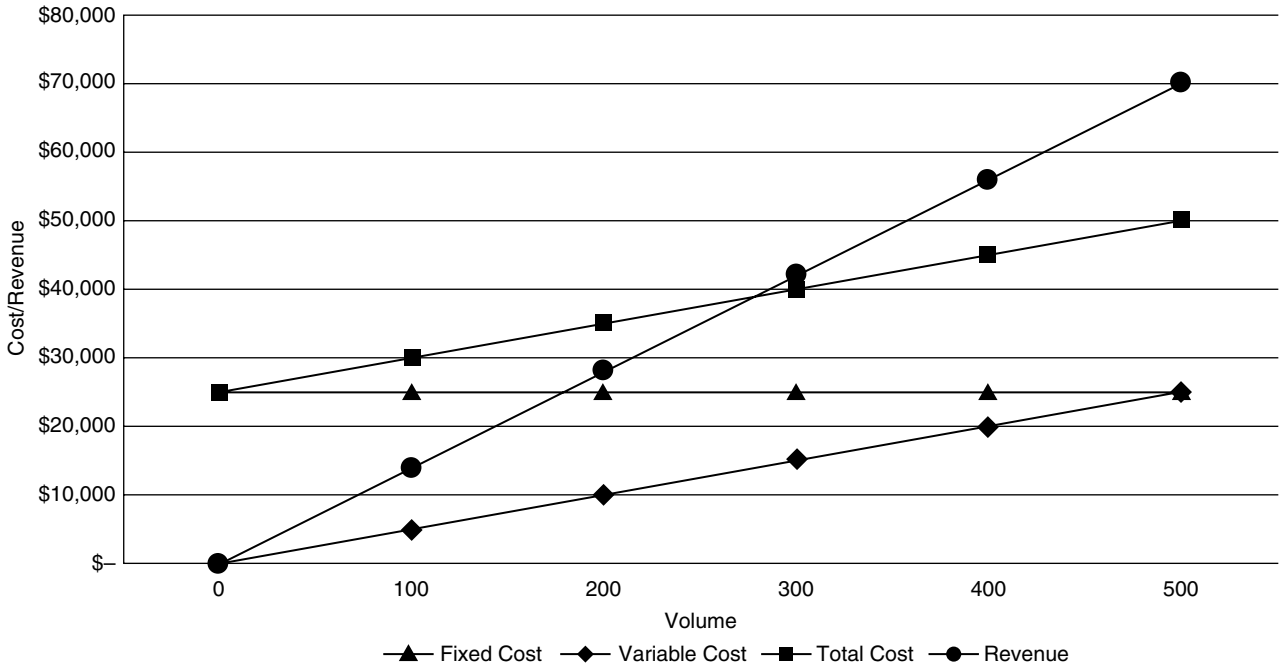


Figure 30.3 Fixed, variable, and total expense and revenue.

5% discount rate, we already know that the present value of \$115.76 after 3 years is \$100.00. For \$120.34 after 4 years,

$$\text{PV} = \frac{\$120.34}{(1+0.05)^4} = \$99.00$$

Therefore, the first choice (3 years) has a higher value.

Investments are evaluated based on their cash flows (CF), where CF = cash revenues – cash expenses. The net present value (NPV) of a project equals the sum of the PV of the CF of the project.

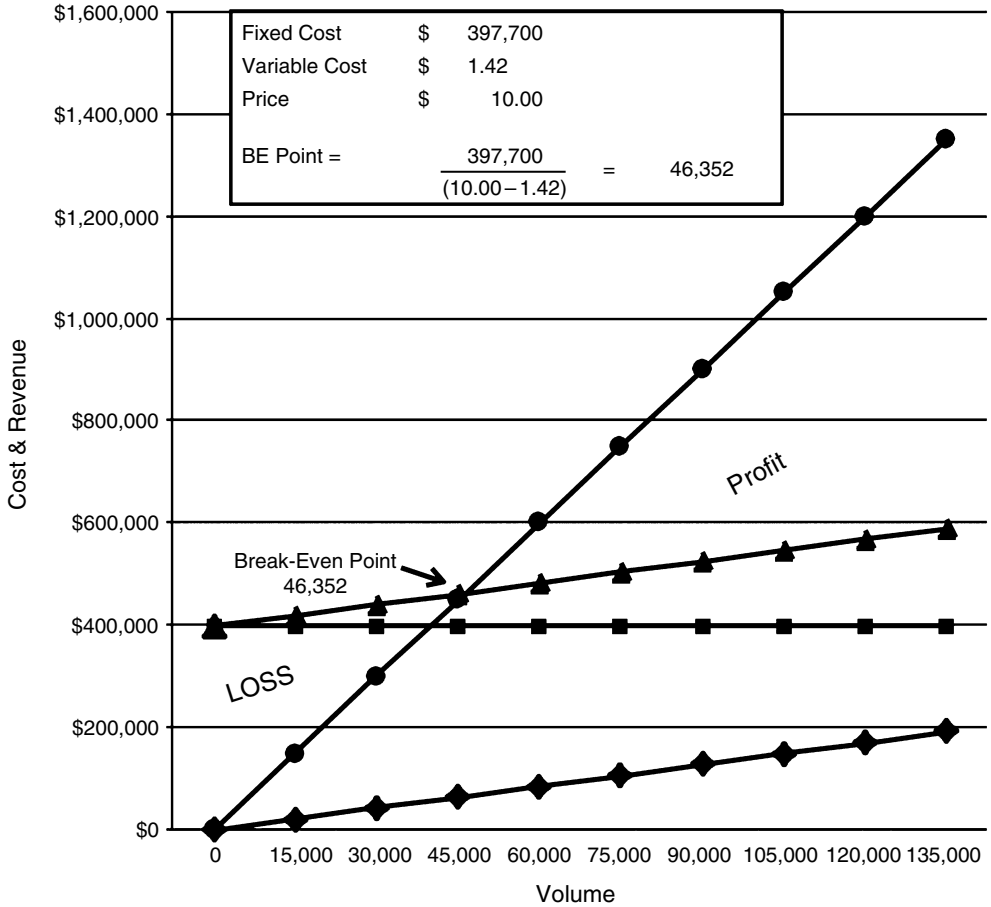


Figure 30.4 Graphical representation of the break-even point for a hematology division.

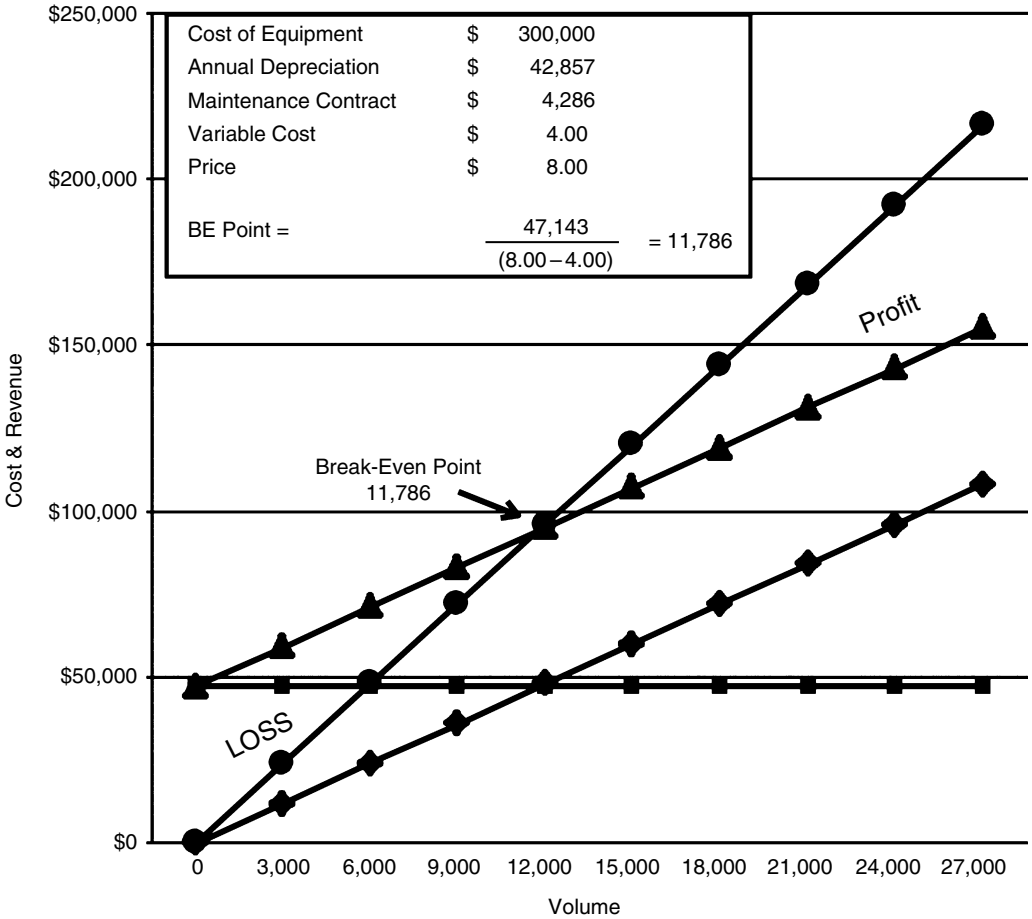


Figure 30.5 Break-even point for equipment purchase.

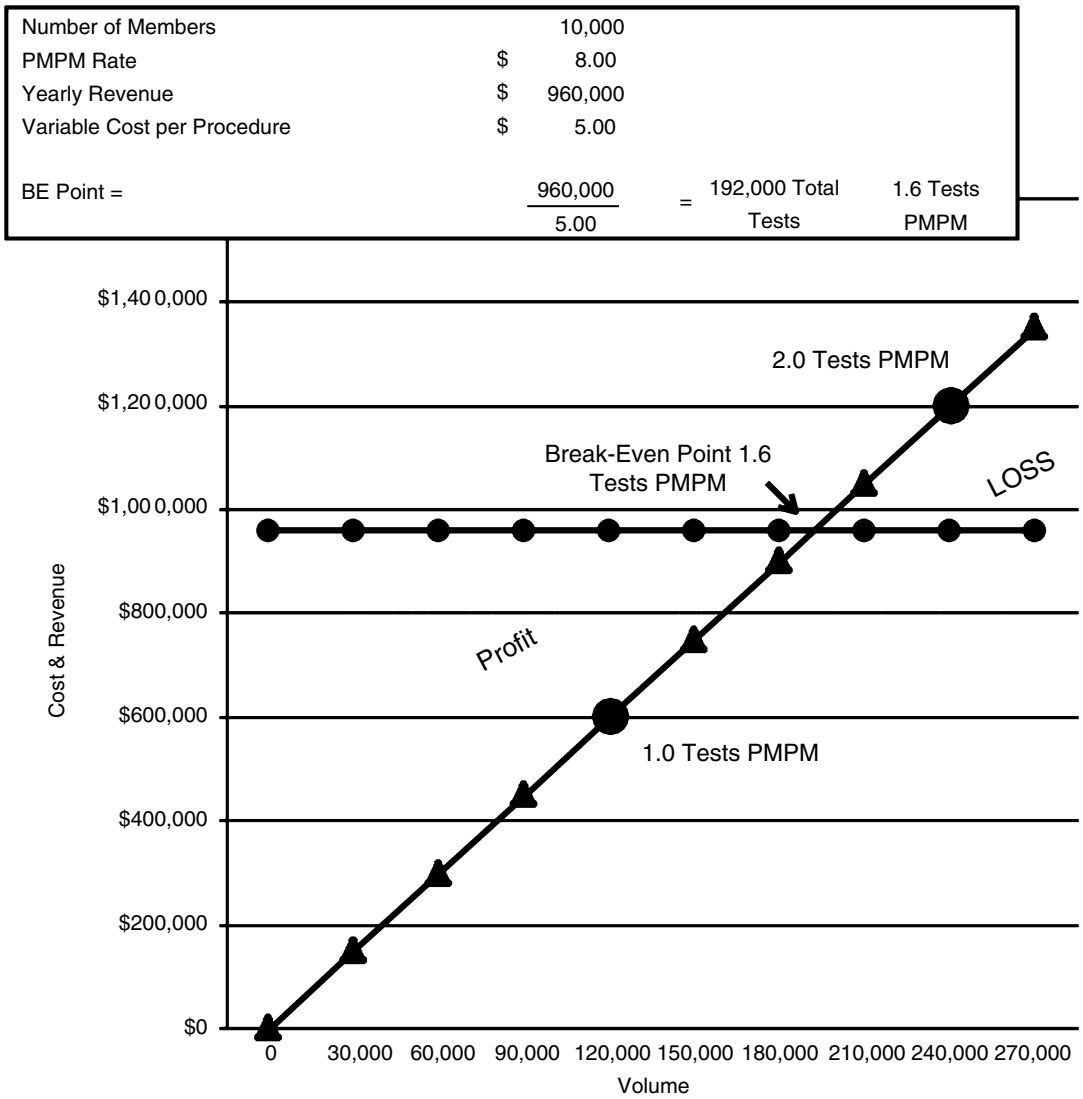


Figure 30.6 Break-even point for a capitated contract.

$$\text{NPV} = \sum_{t=0}^{n} \frac{CF_t}{(1+k)^t}$$

Here, the rate k is referred to as the required rate of return, the cost of capital, or the hurdle rate. If the NPV is >0, the investment is warranted. If NPV is <0, it should not be pursued. If you are comparing two alternatives, pick the one with the higher NPV. A special case is when the NPV = 0. The rate k that induces this is called the internal rate of return (IRR). Instead of calculating the NPV for two competing investments, you can calculate their internal rates of return. Pick the investment with the higher IRR, as long as the IRR is greater than your cost of capital (if it is not, then your capital would be better invested elsewhere). For example, a new analyzer costs $100,000 and will allow the laboratory to perform testing it does not perform today, so it will generate $35,000 in net cash flow per year for the next 4 years. If our required rate of return is 10%, is this a worthwhile investment?

Time	Cash flow
0	–$100,000
1	$35,000
2	$35,000
3	$35,000
4	$35,000

$$NPV = \frac{-\$100,000}{(1+0.10)^0} + \frac{\$35,000}{(1+0.10)^1} + \frac{\$35,000}{(1+0.10)^2} + \frac{\$35,000}{(1+0.10)^3} + \frac{\$35,000}{(1+0.10)^4}$$

$$NPV = \$10,945$$

Solving for the internal rate of return (spreadsheet software and most financial calculators automate this):

$$0 = \frac{-\$100,000}{(1+IRR)^0} + \frac{\$35,000}{(1+IRR)^1} + \frac{\$35,000}{(1+IRR)^2} + \frac{\$35,000}{(1+IRR)^3} + \frac{\$35,000}{(1+IRR)^4}$$

IRR = 14.96%. This IRR would then be compared with the other possible returns the company might get with the money if it were invested in other projects.

Many laboratory investments do not create new revenues, but these same techniques can be applied to calculating net present *cost* and then choosing the option with the lowest cost.

Table 30.7 evaluates a direct purchase versus an installment purchase, where payments are made over time, as an example of a net present cost application. Assume the following: direct purchase price equals $200,000; installment purchase equals $40,000 per year with a useful life of 7 years; discount rate equals 10%. In this example it would be less expensive to purchase the equipment directly than make an installment purchase, $200,000 versus $213,397. Nonetheless, other factors may favor installments, such as available cash.

Table 30.8, the evaluation of two different pieces of laboratory equipment that serve the same function, is an example of calculating the NPVs. Equipment 1 costs $200,000 and generates $60,000 of net cash flow per year for the 7-year useful life of the equipment. Equipment 2 costs $300,000 and generates $90,000 per year for the 7-year useful life of the equipment. The cost of the equipment and depreciation is spread evenly over the 7 years of useful life. Based on these figures, equipment 2 would be chosen over equipment 1 because of its higher NPV—$125,598 versus $83,732.

Depreciation

Depreciation is associated with capital investments, so it is worth commenting on. Depreciation is the allocation of the cost to acquire an asset that has a useful life of greater than 1 year into each year of the asset's life. It is common to use a "straight line" method in healthcare, whereby the depreciation is evenly allocated across the item's useful life. For example, if a piece of equipment costs $100,000 and has a useful life of 10 years, after which it is worth nothing, an annual depreciation expense of $10,000 per year would be recorded for each of the 10 years. There are other methods of depreciation that are driven by tax laws and usually allow for a more accelerated treatment of this expense.

Investment decisions are based on cash flows, and depreciation is not a cash flow. The relevant cash flow is the purchase event. From an accounting standpoint, the organization is simply exchanging one asset, cash, for another, the asset. Depreciation serves to reduce the value of the asset over time on the organization's financial statements, but it should be *ignored* when evaluating capital acquisitions.

Budgeting

It is through budgeting that an organization turns its strategic plans into daily operations. A budget expresses planned revenues and expenses, as well as the volumes of services and amounts of resources required to realize them. Through the budget process the organization establishes priorities for its plans, allocates its resources, and controls its costs. It authorizes new programs and services and sets performance standards for existing ones. A budget thus serves as a tool and a benchmark for monitoring the performance of the organization throughout its fiscal year. In addition, it is a mechanism for imposing discipline on the organization.

Two key concepts are integral to healthcare budgeting: full-time equivalents (FTEs) and UOSs. An FTE is one or more employees paid for a total of 2,080 h per year (based on 8 h per day × 5 days per week × 52 weeks per year); this is the standard labor measure. An employee who is paid for two 8-h days per week represents 0.4 FTE, while an employee who is paid for two 12-h days per week represents 0.6 FTE. Together, they represent 1.0 FTE to the organization. Labor is divided into productive time—the time spent working on job-related activities—and nonproductive time, which includes vacation, holidays, and sick time. Depending on an organization's fringe benefit policies, it will need 1.1 or more FTEs to realize 1.0 FTE of productive time.

Each area of the organization needs a way of quantifying its productivity. As stated earlier, a UOS is the logical measure of work for a given area. In the laboratory, it is usually either the number of billed tests or the number of procedures performed. For the operating room, it may be the number of surgeries; for a physician office, it may be the number of patient visits. UOSs are useful for measuring and comparing resource consumption, such as total expenses per billed test or billed tests per FTE, as we saw in the cost accounting section.

Types of Budgets

Three separate budgets are developed during the budgeting process.

The first, and the one with which you are probably most familiar, is the *operating budget*. This is prepared at the level of the cost center, usually by those managers who have direct responsibility for managing the cost center and

Table 30.7 NPV of direct purchase versus installment purchase

Project	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Discount Rate	10%							
Direct Purchase	$ 200,000							
Installment Purchase	$ 40,000	$ 40,000	$ 40,000	$ 40,000	$ 40,000	$ 40,000	$ 40,000	$ 40,000
NPV of Installment Purchase	$ 213,397							

Table 30.8 NPV of two different pieces of equipment

Project	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Discount Rate	10%							
Equipment #1								
Cost of Equipment	$ (200,000)							
Incremental Revenue		$ 100,000	$ 100,000	$ 100,000	$ 100,000	$ 100,000	$ 100,000	$ 100,000
Incremental Expense		$ (68,571)	$ (68,571)	$ (68,571)	$ (68,571)	$ (68,571)	$ (68,571)	$ (68,571)
Depreciation		$ 28,571	$ 28,571	$ 28,571	$ 28,571	$ 28,571	$ 28,571	$ 28,571
Net Cash Flow	$ (200,000)	$ 60,000	$ 60,000	$ 60,000	$ 60,000	$ 60,000	$ 60,000	$ 60,000
Net Present Value of Cash Flows	$ 83,732							
Equipment #2								
Cost of Equipment	$ (300,000)							
Incremental Revenue		$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000	$ 150,000
Incremental Expense		$ (102,857)	$ (102,857)	$ (102,857)	$ (102,857)	$ (102,857)	$ (102,857)	$ (102,857)
Depreciation		$ 42,857	$ 42,857	$ 42,857	$ 42,857	$ 42,857	$ 42,857	$ 42,857
Net Cash Flow	$ (300,000)	$ 90,000	$ 90,000	$ 90,000	$ 90,000	$ 90,000	$ 90,000	$ 90,000
Net Present Value of Cash Flows	$ 125,598							

who can affect its operations. The operating budget can be broken down into three components:

- *Statistical budget*, or volume budget, which is the forecast of activity for the unit
- *Revenue budget*, which determines the gross charges that will be generated by the forecasted volume
- *Expense budget*, which projects the amounts of resources that will be required to produce the forecasted volumes

The *capital budget* is the second type of budget. Its development can occur simultaneously with the operating budget. It is usually prepared at the organization level and includes new or replacement property, physical plant, and equipment needs of the organization for the coming year. Most organizations have a system in place to collect information on these needs from departments across the organization and then arrange the priorities centrally with respect to acuity of need, organizational goals, and available funding. Capital budgeting is separated from the operating budget because the impact of capital purchases is predominantly on cash, with only the depreciation expense affecting the operating budget (see the previous section's discussion of depreciation).

With the operating and capital budgets prepared, an organization can develop the third type, the *cash budget*. This is usually prepared by the organization's finance department and predicts the cash flows in and out of the organization and the resultant cash availability. While obscure to most, it is the most critical of the three budgets. To remain solvent and thus stay in business, the organization must carefully plan its cash reserves, timing of cash disbursements, and any borrowing and investing activities.

The Budgeting Process

Creating a budget entails a fairly linear set of sequential steps, some of which occur at the organizational level and some that are done at the departmental or cost center levels.

Step 1. Establish organizational goals and objectives. Although the senior management usually sets these, it is not uncommon for departments to develop their own objectives in support of the broader organizational goals. For instance, a hospital may set a goal to expand market share in ABC County by 3%. This, in turn, might lead to a goal of establishing a satellite facility in that county. The laboratory might then establish objectives for equipping and running a laboratory or phlebotomy station at that satellite.

Step 2. Review key environmental factors, such as demographics, political and regulatory issues, competition, technology, and the economy. This function is usually performed at the organizational level, although the laboratory may have unique information about its particular niche, such as the marketing activities of a regional reference laboratory with which it is competing for outpatient testing.

Step 3. Determine starting assumptions about inflation, payment levels, admissions, and other key volumes. This function is usually performed at the organizational level.

Step 4. Develop the statistical budget for each UOS in the organization. This budget is completed at the department level using the information garnered in steps 1 to 3. The laboratory manager will need to consider projections of the number of admissions and the length of stay to forecast volumes of inpatient laboratory tests and will have to estimate the activity for various outpatient departments to forecast volumes of outpatient laboratory tests. If the laboratory is free-standing or has nonaffiliated clients, managers must develop forecasting methods for these markets as well.

Step 5. Develop the revenue budget, based on the statistical volumes forecasted in step 3 multiplied by the applicable charges per UOS, resulting in the gross revenue budget. In most organizations, consideration of contractual allowances, write-offs, and bad debt occurs at the organizational level, for purposes of estimating the net revenue budget.

Step 6. Prepare the expense budget on the basis of the data gathered in steps 1 to 4. Because labor often constitutes roughly 70% of a healthcare organization's budget, the expense budget is frequently broken down separately into a staffing budget and a non-personnel expense budget. The staffing budget takes into account the numbers and types of employees, pay rates, and FTEs required in each cost center. Non-personnel expenses include the various supplies consumed and services utilized to produce the UOS forecasted.

Step 7. Assuming the capital budget was produced in parallel with the previous steps, there is usually a process of negotiation and revision between department heads and senior managers once all of the departments' budgets are rolled into one organizational budget and the operating income is calculated.

Step 8. Develop the cash budget.

Step 9. Continue negotiations and revisions across the organization.

Step 10. Submit the budget to the organization's board of directors for approval. Usually, current year and prior year results form the basis on which the new budget is developed. This process is called incremental budgeting. An alternative used in some organizations is zero-based budgeting. Under this approach, every expenditure must

be justified as if the service were starting from scratch, and it must be established that other ways to provide a service are not more cost-effective. While this can be time-consuming, it forces a regular reexamination of why things are done the way they are and whether they still fit with the organization's mission.

Another refinement to the budget process is the use of flexible budgets. The process that has been described so far results in a fixed budget, one in which an annual budget is developed and approved, after which this agreed-upon budget acts as the yardstick against which monthly performance is monitored. Recall, however, the earlier discussion about cost behavior (fixed, variable, etc.). It is relatively straightforward to divide an organization's expenses into those that vary with changes in UOS and those that do not. Subsequently, the variable portion of the budget may change with volume for purposes of monitoring performance. This approach is known as flexible budgeting.

Budget Examples

Table 30.9 is an example of a staffing worksheet that is prepared to calculate how many FTEs a laboratory division would need for the upcoming fiscal year and the costs associated with those FTEs. In practice, more detailed information is required than just FTEs and hourly rates to generate an accurate staffing budget. A manager also has to break down each employee's hours into the different shifts that he or she works, so that any differential rates can be applied. Examples of typical differential rates would be for weekends, evenings, nights, holidays, overtime, etc. In this example, the manager is requesting 19.36 FTEs, which equates to $998,247 in salary expense and $299,474 in fringe benefit expense (such as payroll taxes, health insurance premiums, etc.). Notice that the salary expense is broken down into productive and nonproductive components. This allocation is commonly done to track nonworked but paid hours versus the actual worked hours.

Table 30.10 is an example of a worksheet that is used to analyze a budget being requested by a manager. In this example, the starting point is a pro forma budget that was calculated by (i) projecting any changes in volume and (ii) using the revenue and expense per UOS from the previous year to adjust both revenues and costs.

This calculation allows for a comparison between what one would expect for revenue and expense, given a certain volume level, and what the manager is actually requesting. The manager will need to present a valid case for deviating from the pro forma budget. Once the differences between the pro forma budget and the requested budget, i.e., the variance, have been resolved with senior management, the last step in the process is to apply inflation factors to the approved budget (if all the variances have been accepted) and generate the final budget for the upcoming fiscal year.

Variance Analysis

Management reporting is a process of communicating actual versus budget performance throughout the organization to identify necessary corrective actions and help make decisions. Distribution of reports usually follows the organizational structure. Detailed line item reports are analyzed at the cost center level. These reports roll up into more and more summaries as one moves up the chain of command. For example, a chemistry supervisor reviews more detail than does the laboratory manager, who looks at summary reports across the laboratory, while the vice president for ancillary services looks at summary reports for the laboratory, radiology, pharmacy, etc.

Variance analysis is critical to the control function of management. Having established a budget, the extent to which actual experience differs from the budget represents a variance. Controllable variances can be resolved by management action. Vendors may be substituted, contracts may be renegotiated, or alternative methodologies may be pursued. Other variances are not controllable, such as a flu epidemic that drives up demand for services above what was budgeted, but as a result may require management to make changes to more discretionary expenditures to offset the uncontrollable epidemic factor. Variance analysis commonly focuses on the company's actual results versus budgeted expectations on a line-by-line basis for each cost center. It is important that the line manager who has the understanding of the cost center and the ability to make any necessary changes should actually perform this analysis. It is the job of the manager to explain the variances to superiors. Table 30.11 is an example of a typical variance report for a laboratory division.

Cost variances can have several causes. Volume variances result from a change in the volume of services performed, either up or down. A flexible budget, described in the previous section, takes account of these variances. At the top of Table 30.11, you can see that volume is under budget by 1,797, or a little less than 1%. Price variances are due to a change in the price of a supply or service versus what was anticipated in the budget. In Table 30.11, laboratory supplies are budgeted at $1.13/UOS, but the actual cost is $0.89, a $0.24 favorable price variance. Quantity, or efficiency, variances represent differences in the amount of inputs (labor and/or supplies) used to produce each UOS. The budget in Table 30.11 considers 16,818 tests per FTE (290,784 tests divided by 17.29 FTEs), and the actual is only 15,792/FTE, so more employee hours are required than was budgeted, an unfavorable quantity variance that helps explain the unfavorable salary dollar variance.

Any variance can be broken down into one of three main causes: volume, price, or quantity. If the cause of the variance is understood, a manager can tailor the response

Table 30.9 Staffing worksheet

JOB			20XX		
Code	**Title**	**Employee Name**	**FTE**	**Hourly Rate**	**Total Pay**
078J	Charge Technologist	Employee Name	1.01	$ 30.15	$ 63,341
078J	Charge Technologist	Employee Name	1.01	$ 30.08	$ 63,194
078J	Charge Technologist	Employee Name	1.00	$ 27.31	$ 56,800
078J Total			**3.02**		**$ 183,335**
078K	Medical Technologist	Employee Name	0.35	$ 23.59	$ 17,171
078K	Medical Technologist	Employee Name	0.76	$ 26.07	$ 41,208
078K	Medical Technologist	Employee Name	0.81	$ 23.68	$ 39,897
078K	Medical Technologist	Employee Name	0.97	$ 26.25	$ 52,972
078K	Medical Technologist	Employee Name	1.02	$ 18.39	$ 39,021
078K	Medical Technologist	Employee Name	0.65	$ 24.23	$ 32,760
078K	Medical Technologist	Employee Name	0.77	$ 26.57	$ 42,556
078K	Medical Technologist	Employee Name	0.75	$ 23.67	$ 36,924
078K	Medical Technologist	Employee Name	0.87	$ 26.51	$ 47,976
078K	Medical Technologist	Employee Name	0.96	$ 19.41	$ 38,758
078K	Medical Technologist	Employee Name	0.35	$ 23.52	$ 17,120
078K	Medical Technologist	Employee Name	0.53	$ 22.14	$ 24,403
078K	Medical Technologist	Employee Name	1.02	$ 21.54	$ 45,699
078K	Medical Technologist	Employee Name	1.01	$ 19.31	$ 40,556
078K	Medical Technologist	Employee Name	0.76	$ 18.88	$ 29,852
078K Total			**11.58**		**$ 546,873**
078L	Medical Lab Technician	Employee Name	0.08	$ 21.45	$ 3,569
078L Total			**0.08**		**$ 3,569**
900A	Sr Medical Technologist	Employee Name	0.27	$ 27.51	$ 15,448
900A	Sr Medical Technologist	Employee Name	0.78	$ 26.35	$ 42,748
900A	Sr Medical Technologist	Employee Name	0.63	$ 27.51	$ 36,045
900A Total			**1.68**		**$ 94,240**
B474	Lab Assistant II	Employee Name	1.00	$ 16.60	$ 34,533
B474 Total			**1.00**		**$ 34,533**
L314	Supervisor Laboratory	Employee Name	1.00	$ 27.33	$ 56,849
L314 Total			**1.00**		**$ 56,849**
L437	Chief Technologist - Lab	Employee Name	1.00	$ 37.91	$ 78,849
L437 Total			**1.00**		**$ 78,849**
			19.36		**$ 998,247**
				Non-Productive Salary	$ 109,807
				Productive Salary	$ 888,440
				Total Salary	$ 998,247
				Fringe @ 30%	$ 299,474

rationally and appropriately. Analysis and reporting of variances are ongoing processes and should be conducted monthly in order to respond quickly. As with cost accounting, however, the effort should be justified by the information gained in the process. Normal random fluctuations will cause small variances, so it is useful to establish triggers to indicate when further investigation is warranted. Control charts, as illustrated in Fig. 30.7, are useful tools for this purpose. In this chart the budget monthly test volume serves as the median line. The upper and lower limits

Table 30.10 Worksheet for constructing a budget

CATEGORY	FY 20XX PROJECTED	FY 20YY PRELIMINARY BUDGET	VOLUME ADJUSTMENT	FY 20YY ADJUSTED PRO FORMA	INFLATION FEE INCREASE ADJUSTMENT	FY 20YY FINAL BUDGET
VOLUME						
Inpatient Volume	155,415	159,897	–	159,897	–	159,897
Outpatient Volume	133,572	130,887	1,000	131,887	–	131,887
Total Volume	288,987	290,784	1,000	291,784	–	291,784
REVENUE						
Inpatient Revenue	3,079,451	3,124,187	–	3,124,187	62,484	3,186,671
Outpatient Revenue	2,540,748	2,471,015	19,022	2,490,037	49,801	2,539,837
Gross Patient Revenue	5,620,199	5,595,202	19,022	5,614,224	112,284	5,726,508
Est Deductions from Revenue	(1,967,070)	(1,958,321)	(6,658)	(1,964,978)	(39,300)	(2,004,278)
Net Patient Revenue	3,653,130	3,636,881	12,364	3,649,245	72,985	3,722,230
EXPENSE						
Non-Productive Salary	95,979	84,823	332	85,155	1,703	86,859
Productive Salary	726,993	686,298	2,516	688,813	13,776	702,590
Overtime	10,016	16,011	35	16,046	321	16,367
Salaries	832,988	787,132	2,882	790,014	15,800	805,815
Fringe	215,411	203,584	745	204,329	4,087	208,416
Payroll Tax & Fringe	215,411	203,584	745	204,329	4,087	208,416
Salaries & Fringe Benefits	1,048,399	990,716	3,628	994,344	19,887	1,014,231
Medical Surgical Supplies	2,633	3,594	9	3,603	72	3,675
Lab Supplies	256,982	328,640	889	329,529	6,591	336,120
Pharmaceutical Supplies	350	312	1	313	6	319
Office Supplies	2,382	3,054	–	3,054	61	3,115
Books/Subscriptions/Dues	–	250	–	250	5	255
Travel/Meetings	3,043	3,349	–	3,349	67	3,416
Maintenance Contracts	34,808	44,000	–	44,000	880	44,880
Celebration/Food	180	350	–	350	7	357
Small Equipment	2,174	2,647	–	2,647	53	2,700
Total Non-Salary Expense	302,552	386,196	900	387,096	7,742	394,837
Total Expense	1,350,951	1,376,912	4,527	1,381,439	27,629	1,409,068
Contribution Margin	2,302,179	2,259,969	7,837	2,267,806	45,356	2,313,162
STATISTICS						
Contribution Margin Percent	63.0%	62.1%	63.4%	62.1%	0.0%	62.1%
Total FTEs	18.30	17.29	0.06	17.35	–	17.35
Hours per UOS	0.13	0.12	0.12	0.12	–	0.12
Revenue per UOS	12.64	12.51	12.36	12.51	–	12.76
Expense per UOS	4.67	4.74	4.53	4.73	–	4.83
Contribution per UOS	7.97	7.77	7.84	7.77	–	7.93

Table 30.11 Variance report

CATEGORY	FY 20YY ACTUAL	FY 20YY BUDGET	VARIANCE	PERCENT VARIANCE
VOLUME				
Inpatient Volume	155,415	159,897	(4,482)	–2.80%
Outpatient Volume	133,572	130,887	2,685	2.05%
Total Volume	288,987	290,784	(1,797)	–0.62%
REVENUE				
Inpatient Revenue	3,079,451	3,124,187	(44,736)	–1.43%
Outpatient Revenue	2,540,748	2,471,015	69,733	2.82%
Gross Patient Revenue	5,620,199	5,595,202	24,997	0.45%
Est Deductions from Revenue	(1,967,070)	(1,958,321)	(8,749)	0.45%
Net Patient Revenue	3,653,130	3,636,881	16,248	0.45%
EXPENSE				
Non-Productive Salary	95,979	84,823	11,156	13.15%
Productive Salary	726,993	686,298	40,695	5.93%
Overtime	10,016	16,011	(5,995)	–37.44%
Salaries	832,988	787,132	45,856	5.83%
Fringe	215,411	203,584	11,827	5.81%
Payroll Tax & Fringe	215,411	203,584	11,827	5.81%
Salaries & Fringe Benefits	1,048,399	990,716	57,683	5.82%
Medical Surgical Supplies	2,633	3,594	(961)	–26.74%
Lab Supplies	256,982	328,640	(71,658)	–21.80%
Pharmaceutical Supplies	350	312	38	12.26%
Office Supplies	2,382	3,054	(672)	–21.99%
Books/Subscriptions/Dues	–	250	(250)	–100.00%
Travel/Meetings	3,043	3,349	(306)	–9.14%
Maintenance Contracts	34,808	44,000	(9,192)	–20.89%
Celebration/Food	180	350	(170)	–48.57%
Small Equipment	2,174	2,647	(473)	–17.88%
Total Non-Salary Expense	302,552	386,196	(83,644)	–21.66%
Total Expense	1,350,951	1,376,912	(25,961)	–1.89%
Contribution Margin	2,302,179	2,259,969	42,209	1.87%
STATISTICS				
Contribution Margin Percent	63.0%	62.1%	0.9%	1.41%
Total FTEs	18.30	17.29	1.01	5.86%
Hours per UOS	0.13	0.12	0.01	6.51%
Revenue per UOS	12.64	12.51	0.13	1.07%
Expense per UOS	4.67	4.74	(0.06)	–1.28%
Contribution per UOS	7.97	7.77	0.19	2.50%

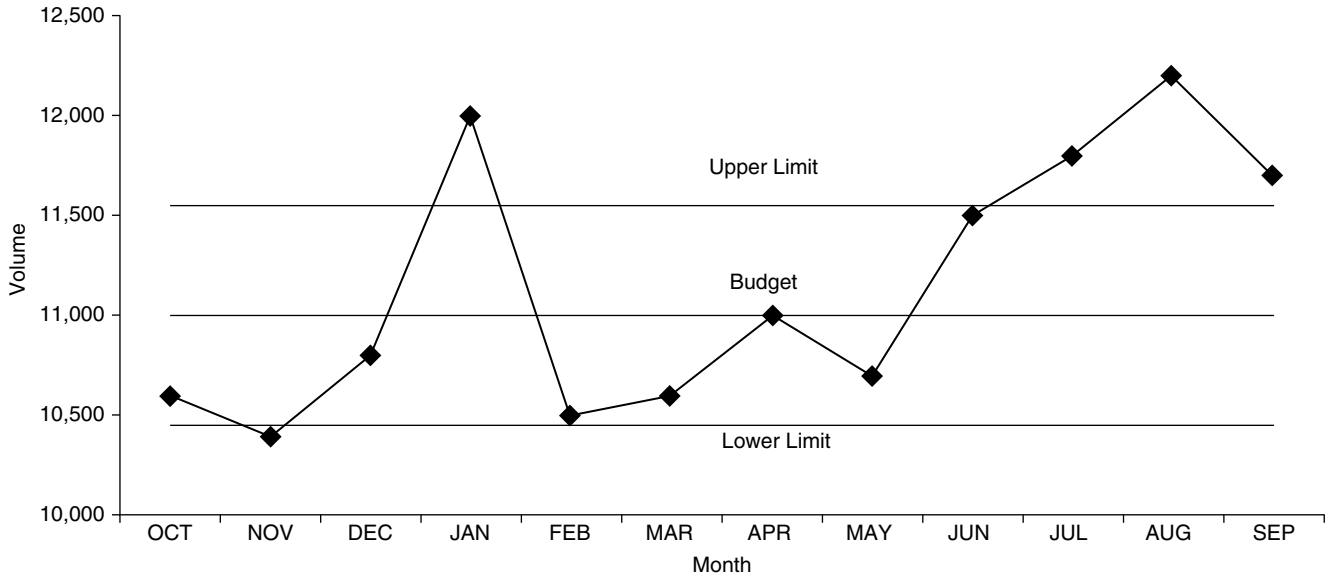


Figure 30.7 Volume control chart.

represent arbitrary figures that are 5% above and below the budgeted volume.

Variations in labor, which can be further analyzed, are important because labor costs constitute such a large portion of expenses. Both labor costs and hours can be divided into worked and paid categories. The duties of workers who are vacationing, attending conferences, sick, or injured must be assumed by others; the proportion of costs due to a reduction in worked versus paid time may be important for the organization. Worked time can be further subdivided into productive and nonproductive. The variance due to assuming the duties of staff who are attending a conference is considered nonproductive worked time. Only if such expenses are adequately identified and characterized can a rational decision be made as to whether they are justified by sufficient benefit to the organization. At the bottom of Table 30.11, one can see that in this example FTEs are over budget by 1.01, or 5.86%.

Laboratory productivity, defined as the UOSs produced divided by the laboratory inputs required to produce them (in either hours or cost), should be benchmarked against regional and national peers to gauge the laboratory efficiency of the organization. At the bottom of Table 30.11, you can see that for this example hours per UOS are over budget by 0.01, or 6.51%. This variance is caused by a combination of volume being slightly under budget and FTEs being over budget.

Financial Statements

In the previous section, we discussed internal reporting and variance analysis, which management uses to control expenses and help make decisions. In this section, we turn to external reporting of an organization's finances. The various groups of people interested in the financial health of an organization include stockholders who have invested in the company (or potential stockholders), creditors who might loan the company money, and government agencies that regulate the company. Management itself also uses financial statements to help monitor the activities of the firm.

The three primary financial statements are the balance sheet, the income statement, and the cash flow statement. The balance sheet (Table 30.12) is a snapshot of a firm's financial position at a particular point. It has two sections: assets and equities. Assets are economic resources that are expected to benefit the company's activities. Equities are claims against or interests in the assets. Equities are divided into liabilities and owners' equity. Liabilities are economic obligations of the organization. Owners' equity (usually called stockholders' equity) is the ownership claim against the total assets. Balance sheet account balances carry over from year to year, whereas income statement account balances start from zero at the beginning of each new fiscal year.

The income statement in Table 30.13 reports the results of a firm's operations over a period of time by matching its revenues to its expenses, while the cash flow (CF) statement in Table 30.14, also called the statement of changes in financial position, reports the impact of operating, investing, and financing activities over a period of time. Its purpose is to present the results of financial management, as opposed to the operating management reflected in the income statement.

Financial Ratios

Several key indicators, expressed as ratios, can help us understand the financial health of an organization as

Table 30.12 Balance sheet for an organization as of September 20YY

Assets / Liabilities & Stockholder Equity	Sept 30 20XX		Sept 30 20YY	
ASSETS				
Current Assets				
Cash	15,000,000		13,200,000	
Short-Term Investments	50,000,000		42,000,000	
Accounts Receivable	140,000,000		145,000,000	
Contractual Allowance Reserve	(60,000,000)		(62,000,000)	
Inventories	5,000,000		5,500,000	
Prepaid Expenses	2,000,000	152,000,000	1,500,000	145,200,000
Fixed Assets				
Equipment	300,000,000		320,000,000	
Furniture & Fixtures	150,000,000		160,000,000	
Leasehold Improvements	200,000,000		205,000,000	
Accumulated Depreciation	(400,000,000)	250,000,000	(419,000,000)	266,000,000
Other Assets		7,000,000		7,500,000
Total Assets		409,000,000		418,700,000
LIABILITIES & STOCKHOLDER EQUITY				
Current Liabilities				
Accounts Payable	8,000,000		7,000,000	
Accrued Expenses	20,000,000		19,000,000	
Short-Term Portion of Notes Payable	5,000,000	33,000,000	4,500,000	30,500,000
Long-Term Liabilities				
Capital Lease Obligations	1,000,000		750,000	
Long-Term Portion of Notes Payable	90,000,000	91,000,000	85,000,000	85,750,000
Stockholder Equity				
Common Stock	185,000,000		185,000,000	
Retained Earnings	100,000,000	285,000,000	117,450,000	302,450,000
Total Liabilities & Stockholder Equity		409,000,000		418,700,000

represented in its statements. There are four categories of financial ratios:

- Liquidity ratios measure the ability of a firm to meet its immediate obligations, i.e., the relationship between a firm's cash and other current assets to its current liabilities.
- Asset management, or activity, ratios measure how effective a firm is at managing its assets.
- Debt management, or leverage, ratios measure both the extent to which the firm is financed with borrowing and its likelihood of defaulting on its debt obligations.
- Profitability ratios measure the combined effects of liquidity, asset management, and debt management policies on operating results.

Although the financial ratio values themselves, or their trends over time, provide useful information, their greater value comes from comparing them to industry averages. As an example, the automotive industry, with its well-established firms, will have a very different financial structure than firms in the Internet industry. A negative profitability ratio in the automotive industry would be viewed as a sign of poor financial health, but in the Internet industry it may not be viewed this way (or,

Table 30.13 Income and expense statement for an organization, year-to-date September 20YY

Revenue & Expenses	YTD Actual	YTD Budget	YTD Variance	Percent Variance
REVENUES				
Patient Service Revenue				
Inpatient Revenue	250,000,000	260,000,000	(10,000,000)	–3.85%
Outpatient Revenue	120,000,000	105,000,000	15,000,000	14.29%
Physician Revenue	170,000,000	160,000,000	10,000,000	6.25%
Total Patient Service Revenue	540,000,000	525,000,000	15,000,000	2.86%
Deductions From Revenue				
Blue Cross	26,000,000	25,000,000	1,000,000	4.00%
Medicare	58,000,000	57,000,000	1,000,000	1.75%
Medicaid	16,000,000	16,000,000	–	0.00%
Commercial	26,000,000	25,000,000	1,000,000	4.00%
Managed Care	25,000,000	25,000,000	–	0.00%
Contractual Allowance Reserve	9,500,000	9,500,000	–	0.00%
Total Deductions From Revenue	160,500,000	157,500,000	3,000,000	1.90%
Net Patient Service Revenue	379,500,000	367,500,000	12,000,000	3.27%
Other Revenue	10,000,000	9,500,000	500,000	5.26%
Total Revenue	389,500,000	377,000,000	12,500,000	3.32%
EXPENSES				
Salary & Fringe				
Physician Salary	60,000,000	59,500,000	500,000	0.84%
Staff Salary	125,000,000	124,000,000	1,000,000	0.81%
Physician Fringe	18,000,000	17,850,000	150,000	0.84%
Staff Fringe	31,250,000	31,000,000	250,000	0.81%
Total Salary & Fringe	234,250,000	232,350,000	1,900,000	0.82%
Medical Supplies	30,000,000	28,500,000	1,500,000	5.26%
Pharmaceuticals	15,000,000	14,000,000	1,000,000	7.14%
Utilities	8,000,000	7,500,000	500,000	6.67%
Insurance	7,000,000	6,500,000	500,000	7.69%
Purchased Service	14,000,000	14,000,000	–	0.00%
Other Expenses	28,000,000	27,500,000	500,000	1.82%
Depreciation	19,000,000	19,000,000	–	0.00%
Interest Expense	5,000,000	5,500,000	(500,000)	–9.09%
Provision for Bad Debt	16,000,000	15,750,000	250,000	1.59%
Total Expense	376,250,000	370,600,000	5,650,000	1.52%
Income From Operations	13,250,000	6,400,000	6,850,000	107.03%
NON-OPERATING GAINS				
Non-Operating Gains				
Unrestricted Gifts	400,000	500,000	(100,000)	–20.00%
Investment Income	12,000,000	13,000,000	(1,000,000)	–7.69%
Income from Affiliates	(200,000)	100,000	(300,000)	–300.00%
Unrealized Gain/Loss	(8,000,000)	(5,000,000)	(3,000,000)	60.00%
Total Non-Operating Gains	4,200,000	8,600,000	(4,400,000)	–51.16%
Revenue & Gains in Excess of Expenses	17,450,000	15,000,000	2,450,000	16.33%

Table 30.14 Cash flow statement for an organization, September 20YY

CASH FLOWS FROM OPERATING ACTIVITIES & GAINS	
Revenue & Gains in Excess of Expenses	17,450,000
Depreciation & Amortization	19,000,000
Unrealized Gain/Loss	8,000,000
Decrease (Increase) in Accounts Receivable	(5,000,000)
Decrease (Increase) in Inventories	(500,000)
Increase (Decrease) in Contractual Allowance Reserve	2,000,000
Increase (Decrease) in Accounts Payable	(1,000,000)
Increase (Decrease) in Accrued Expenses	(1,000,000)
Net Cash Flow Provided by Operating Activities & Gains	38,950,000
CASH FLOWS FROM INVESTING ACTIVITIES	
Purchase of Fixed Assets	(35,000,000)
Increase (Decrease) in Notes Payable	(5,500,000)
Increase (Decrease) in Capital Lease Obligations	(250,000)
Increase (Decrease) in Common Stock	–
Net Cash Provided by Investing Activities	(40,750,000)
Cash at Beginning of Reporting Period - 09/30/20XX	15,000,000
Cash at End of Reporting Period - 09/30/20YY	13,200,000

at least, so it was once thought). Table 30.15 shows the financial ratios for the financial statements shown in Tables 30.12 through 30.14.

Applications of Financial Tools in the Evolving Laboratory Landscape

Developments such as the ongoing move toward value-based payment models and the COVID-19 pandemic have placed a premium on laboratory managers' abilities to apply the principles of accounting and financial analysis to navigate major changes in their operating contexts. The traditional fee-for-service model has long rewarded volume and efficiency; increasing test volumes with low marginal cost can significantly impact contribution margin. The ongoing migration toward value-based approaches has challenged managers to intensify their efforts to optimize components of the preanalytical and postanalytical phases, as ensuring appropriateness of test orders and usability of test results can drive savings for the overall health system (8).

The onset of the COVID-19 pandemic prompted rapid changes in laboratory operations and finances, with the sudden drop in usual clinical services prompting a decrease in the associated laboratory testing and disruption of cash flow, even as the need to bring COVID-19 testing online rapidly and at scale necessitated investment in instrumentation and expenditures to procure reagents and supplies that were frequently supply-constrained (9). Year-to-year changes in budgets were often relatively small in prepandemic times, but the greater unpredictability now confronting healthcare organizations has prompted some laboratories and health systems to move from fixed annual budgeting to flexible budgeting, in which adjustments can be made more frequently based on changing circumstances.

SUMMARY

In this chapter, we began with cost accounting and discussed the types and behaviors of costs. Direct costs are clearly associated with the item being costed, while all other costs are indirect. The behavior of costs relative to changes in volume can be variable (in direct proportion to volume) or fixed (constant regardless of volume) or some combination thereof. We reviewed how to measure full cost and how it differs from marginal cost, which is the change in total cost relative to a change in volume. An extensive costing example showed what data are needed to generate a cost analysis and how to cost a basic laboratory test.

Understanding the relationships among cost, volume, and profits allowed us to calculate contribution margin—the revenue per UOS less its marginal cost—and break-even point, which is total fixed cost divided by the contribution margin per UOS. These concepts were applied to an

Table 30.15 Ratio analysis for an organization, September 20YY

Financial Ratios	Equation	September 30, 20XX			September 30, 20YY			Industry Average
LIQUIDITY RATIOS								
Current Ratio	Current Assets	152,000,000			145,200,000			
	---	---	=	4.6	---	=	4.8	4.0
	Current Liabilities	33,000,000			30,500,000			
Quick Ratio	Cash + Accts Receivable	95,000,000			96,200,000			
	---	---	=	2.9	---	=	3.2	3.0
	Current Liabilities	33,000,000			30,500,000			
ACTIVITY RATIOS								
Days in A/R	Accts Receivable × 365	51,100,000,000			52,925,000,000			
	---	---	=	138	---	=	136	140
	Sales	370,000,000			389,500,000			
Days Cash on Hand	Cash + ST Investments	65,000,000			55,200,000			
	---	---	=	68	---	=	56	52
	(Expense - Deprec) / 365	957,397			978,767			
DEBT MANAGEMENT RATIOS								
Debt Ratio	Total Liabilities	124,000,000			116,250,000			
	---	---	=	30.32%	---	=	27.76%	35.00%
	Total Assets	409,000,000			418,700,000			
Times Interest Earned	Net Profit Before Interest	10,150,000			12,450,000			
	---	---	=	2.0	---	=	2.5	1.5
	Interest Expense	5,000,000			5,000,000			
PROFITABILITY RATIOS								
Return on Total Assets	Net Profit	15,150,000			17,450,000			
	---	---	=	3.70%	---	=	4.17%	3.50%
	Total Assets	409,000,000			418,700,000			
Return on Stockholder Equity	Net Profit	15,150,000			17,450,000			
	---	---	=	5.32%	---	=	5.77%	7.00%
	Stockholder Equity	285,000,000			302,450,000			
Return on Permanent Capital	Net Profit	15,150,000			17,450,000			
	---	---	=	4.03%	---	=	4.50%	4.00%
	Equity + LT Liabilities	376,000,000			388,200,000			
Profit Margin	Net Profit	15,150,000			17,450,000			
	---	---	=	4.09%	---	=	4.48%	6.00%
	Sales Revenue	370,000,000			389,500,000			

equipment purchase and to evaluating a capitation contract. The equipment purchase decision was then augmented by applying time-value-of-money concepts to capital acquisition plans using the NPV and IRR calculations. These techniques allow for acquisitions with different future cash flow patterns to be compared in today's dollars. We looked at purchasing versus leasing and compared two pieces of equipment using these techniques.

We then turned to the budget process and reviewed the three common types of budgets: the operating budget (which consists of a statistical, or volume, budget; a revenue budget; and an expense budget), the capital budget, and the cash budget. We learned the concepts of FTE and UOS, two key building blocks in budget development. We walked through the 10 steps of the budgeting process and illustrations of staffing and budget worksheets. With the budget as the baseline, we looked at management reporting and how to analyze the causes of differences in actual financial performance from budgeted amounts. We broke variances down into one of three causes: volume, price, or quantity variances. Finally, we discussed the importance of understanding which factor is responsible in order to direct the manager's response.

We learned about the three primary financial statements: the balance sheet is a snapshot of the company's financial condition at a given point in time and is a cumulative statement; the income statement reports the results of the company's operations over a period of time; the cash flow statement presents the results of financial, as opposed to operating, management of the company. We used four types of financial ratios to reveal information about an organization's financial health from its financial statements: liquidity ratios, asset management ratios, debt management ratios, and profitability ratios. Ratios are best used in comparison to other companies in the same industry.

KEY POINTS

- Cost accounting is an important tool for controlling expenses and making good resource allocation decisions.
- Marginal costs and the break-even point are relevant when considering taking on additional work.
- Capital investments, such as equipment purchases, require an NPV approach to decision making.
- Budget creation and monitoring should be vested in the managers responsible for implementing the changes that affect the budget.
- Regular variance analysis, especially in regard to labor, is critical to managing within a budget.
- Financial statements and their corollary financial ratios are useful for benchmarking against other organizations in the same industry.

GLOSSARY

Accounts receivable Money that is owed to the firm by outsiders.

Accrual accounting System that records revenue and expenses as they occur.

Asset (and asset accounts) The resources owned or used by the firm.

Asset management ratios Measure of how effective the firm is at managing its assets.

Average cost Full cost divided by the unit of service.

Bad debt Recorded as an expense for gross charges that are deemed uncollectable from self-payors.

Balance sheet Shows assets on the left side and liabilities or claims against assets on the right side. The balance sheet shows a firm's financial position at a particular point in time.

Break-even point The level of activity at which revenue and total costs are exactly equal.

Capital The cash required to purchase the firm's property, plant, and equipment.

Capital budget The financial plan for the acquisition of capital assets.

Capital lease A lease in which the firm retains ownership of the asset at the end of the lease period.

Capitation A reimbursement mechanism in which the service provider receives a fixed payment based on the number of covered lives. The payment does not fluctuate with the level of activity.

Cash accounting Records revenue and expenses when the cash has either been paid out or collected.

Cash budget The cash management plan for how the operational and capital budgets will be supported.

Cash flow Cash revenues less cash expenses; excludes noncash expenses such as depreciation.

Cash flow statement Reports the impact on cash flow of a firm's operating, investing, and financing activities over a period of time.

Contractual allowances Discounts on gross charges given to third-party payors who have a negotiated contract with the billing provider.

Contribution margin The excess of revenue over variable costs.

Cost accounting A system of measuring and reporting information about cost.

Debt management ratios Measure of both the extent to which the firm is financed with borrowing and its likelihood of defaulting on its debt obligations.

Depreciation An annual charge of an asset's cost into each year of the asset's useful life, for assets that have a useful life of greater than 1 year.

Direct allocation Allocates costs of each service department directly and only to revenue-producing responsibility centers.

Direct cost A cost that can be traced to, or caused by, a particular service, product, segment, or activity of the department.

Discount rate The rate used to calculate the present value of future cash flows.

Equity Claims against, or interests in, the assets of a company; divided into liabilities and owners' equity.

Expense budget The amount of resources that will be required to produce the forecasted activity.

Fiscal year The year on which the general ledger is based. It can be different from the calendar year. The fiscal year used by a firm is usually based on the norm of the industry to which it belongs.

Fixed budget A budget in which the budgeted amounts do not fluctuate with the volume.

Fixed costs Costs whose total remains constant regardless of changes in level of activity.

Flexible budget A budget in which the variable portion of the budget fluctuates with the level of volume.

Full-time equivalent (FTE) The proportion of an employee's paid hours per year to the standard labor measure, which is typically 2,080 h (8 h × 5 days × 52 weeks per year).

Fund accounting A form of accounting in which revenues and expenses must always be equal and expenses are stopped when revenue is exhausted.

Future value (FV) The amount to which a given amount of cash will grow at the end of a given period of time when compounded at a given rate of interest.

General ledger The system that records all accounting activity.

Income statement Reports the financial results of a firm's operations over a period of time.

Incremental budgeting Uses prior year results as a basis for building the current year budget.

Indirect cost A cost that cannot be traced to a particular service, product, segment, or activity.

Interest rate The amount charged by lending institutions for the use of the money borrowed by a firm.

Internal rate of return (IRR) The rate that equates the present value of a project's expected cash inflows to the present value of the project's costs.

Liabilities (and liability accounts) The debts or obligations owed to outsiders.

Liquidity ratio Measure of the firm's ability to meet its immediate obligations; thus, the relationship between a firm's current assets and its current liabilities.

Long-term debt The firm's obligations that are due after more than a year.

Management reporting A process of communicating actual versus budgeted performance throughout the organization to identify necessary corrective actions and help make decisions.

Marginal cost The change in total cost relative to the change in volume, i.e., the cost of producing one more unit of service; incremental cost.

Net present value (NPV) The present value of future net cash flows, discounted at the cost of capital.

Nonproductive time Paid time for non-job-related activities such as vacation, holidays, and sick time.

Operating budget The financial plan for managers with direct responsibility for managing the operations of a responsibility center(s). The operating budget is made up of a statistical budget, a revenue budget, and an expense budget.

Overhead costs Costs that are from non-revenue-generating departments.

Owners' equity The ownership claim against the total assets of a company (also called stockholders' equity).

Present value (PV) The value today of a future cash flow.

Price variance The difference between the price of a supply or service versus the price that was budgeted.

Productive time Paid time for job-related activities.

Profitability ratios Measure of the combined effects of liquidity, asset management, and debt management policies on operating results.

Quantity variance The difference between the amount of inputs (labor and/or supplies) used to produce each unit of service versus the quantity that was budgeted.

Required rate of return Known as the hurdle rate or cost of capital, it represents the minimum return on investment a firm requires on capital expenditures.

Revenue budget The revenue that will be generated by the forecasted activity for a responsibility center.

Semivariable costs Costs that include both variable and fixed-cost elements.

Standard cost A measure of how much an item should cost, rather than a record of how much it actually did.

Statistical budget The forecast of activity for a responsibility center.

Step-down allocation Distributes the costs of the service departments providing the most services to all departments. All remaining service departments' costs are then allocated in descending order determined by the amount of service they render.

Step-fixed costs Costs that are fixed over a range of activity and are then increased when activity levels go up.

Stockholder equity accounts The difference between a firm's assets and liabilities (claims against assets). The accounts are reported on the balance sheet and have natural credit balances.

Time value of money A concept that recognizes that a dollar of cash today is worth more than a dollar of cash to be received at some time in the future.

Unit of service (UOS) The logical measure of work for a given area. In the laboratory, it is usually the number of billed tests or procedures performed.

Variable costs Items of cost that vary, in total, directly, and proportionately with volume or level of activity changes.

Variance analysis The process of analyzing differences in actual versus budgeted performance to identify necessary corrective actions and help make decisions.

Volume variance The difference between the volume of services performed versus the volume that was budgeted.

Write-offs Recorded reductions in revenue for gross charges that are deemed uncollectable from third-party payors.

Zero-based budgeting A budgeting methodology in which every expenditure must be justified regardless of the prior year's results.

REFERENCES

1. **Finkler SA**. 1994. *Cost Accounting for Health Care Organizations*. Aspen Publishers, Inc, Gaithersburg, MD.

2. **Horngren CT**. 1984. *Introduction to Management Accounting*, 6th ed. Prentice-Hall, Inc, Englewood Cliffs, NJ.

3. **Joy OM**. 1983. *Introduction to Financial Management*, 3rd ed. Richard D. Irwin, Inc, Homewood, IL.

4. **Pavlock EJ**. 1994. *Financial Management for Medical Groups*. Medical Group Management Association, Englewood, CO.

5. **NCCLS**. 1998. Basic cost accounting for clinical services. Approved Guideline GP11-A, vol 18, no 14. Clinical and Laboratory Standards Institute, Wayne, PA.

6. **CLSI**. 2020. Understanding the cost of quality in the laboratory: a report. 2nd ed. QMS20-R/ed 2, vol 40, no 15. Clinical and Laboratory Standards Institute, Wayne, PA.

7. **CMS**. 2023. Clinical diagnostic laboratory fee schedule, CY 2023 Q2 release. https://www.cms.gov/medicare/medicare-fee-service-payment/clinicallabfeesched/clinical-laboratory-fee-schedule-files/23clabq2. Accessed 10 September 2023.

8. **Plebani M.** 2015. Clinical laboratories: production industry or medical services? *Clin Chem Lab Med* **53**:995–1004.

9. **Jackson BR**, **Genzen JR**. 2021. The lab must go on: clinical laboratory management in a world turned upside down. *Am J Clin Pathol* **155**:4–11.

本书版权归John Wiley & Sons Inc.所有

VI

Coding, Billing, and Charges for Laboratory Services

(SECTION EDITORS: **Vickie S. Baselski and Alice S. Weissfeld**)

31 Correct Coding of Billable Services in the Clinical Laboratory
Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

32 Approaches to Billing Laboratory Services
Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

33 Charges and Fees for Laboratory Services
Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

本书版权归John Wiley & Sons Inc.所有

本书版权归John Wiley & Sons Inc.所有

31

Introduction
Procedure Coding: What Test Procedures Have Been Performed?
The CPT System
Description • Types of CPT Codes • Modifiers • The Process for Change • Procedure Coding Guidance: The Impact on Reimbursement
Procedure Coding Alternatives
Capitated Services
Diagnosis Coding: Why Is the Service Being Performed?
Inpatient Diagnosis Coding • Outpatient Diagnosis Coding • Other Unique Patient Groups • ICD-CM • SNOMED CT
Service Location
Role of CLIA and State Licensing • Revenue Codes
Documentation of Codes
Requisition • Claims • Code Mapping
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES
APPENDIXES

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch31.

Correct Coding of Billable Services in the Clinical Laboratory

Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

OBJECTIVES

To explain the importance of using the standardized coding systems recognized by payors

To discuss laboratory responsibilities to ensure that correct and complete coding has been done

To describe the importance of the ICD-CM coding system and its relationship to proper billing

To discuss the fundamental principles of correct and complete coding

Let the good service of well-deservers be never rewarded with loss. Let their thanks be such as may encourage more strivers for the like.

Elizabeth I (1533–1603),
Queen of England (1558–1603)

THE PRIMARY GOAL OF LABORATORY MEDICINE is to provide a variety of laboratory services that facilitate the role of physicians and other direct healthcare providers in the prevention, diagnosis, treatment, and prognosis of diseases by generating data upon which clinical decisions are made. It has been estimated that although laboratory medicine accounts for only 5 to 7% or less of total healthcare costs, the information generated drives 60 to 70% of subsequent resource utilization and is estimated to direct up to 80% of all clinical decision making (1). In turn, laboratory payments constitute a very low percentage of actual payments to healthcare providers. For example, laboratory services represent just under 2% of program spending for Medicare Part B outpatient healthcare services and just over 2% of national healthcare expenditures (2). By any standard, these figures demonstrate that laboratory medicine services are a bargain as well as a critical component in the provision of healthcare services. As a critical component of healthcare, it is essential that a uniform approach to documenting laboratory services be used to track utilization (3). The critical parameters that one must specify in accounting for laboratory services include (i) the actual laboratory service (i.e., what test procedures the laboratory performed), (ii) the clinical reason for performing the laboratory service (i.e., why the test procedures were performed), and (iii) the specific laboratory type (i.e., the setting in which the work was performed). For each of these parameters, the laboratory must use standard language to communicate with payors and for use in benchmarking comparisons of practices to assess efficiency and effectiveness of services provided.

本书版权归John Wiley & Sons Inc.所有

Reader please note that the Glossary and Appendixes for the three chapters in this section are combined and provided at the end of this chapter.

Procedure Coding: What Test Procedures Have Been Performed?

A number of procedure coding systems have been developed to standardize the documentation of services rendered for financial purposes, although one particular system is primarily used in the United States and is also in use in many other countries. The predominant procedure coding system is the Current Procedural Terminology (CPT) system (4). This system is recognized by the U.S. federal healthcare payment programs (i.e., Centers for Medicare and Medicaid Services, CMS) as the official coding system and has been adopted in its entirety as the federal procedure coding system known as the Healthcare Common Procedure Coding System (HCPCS). For procedures or practices not yet defined by a CPT code, additional HCPCS codes may be established that are used until an appropriate CPT code is available (5). The CPT system is recognized by all other major third-party payors; thus, the oft-stated adage that "as goes Medicare, so go others" is clearly applicable to procedure coding. The CPT system has also been designated as the Standard Electronic Healthcare Transaction Code Set for procedures under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). However, it should be recognized that alternatives do exist, and it was a recommendation of the 2000 Institute of Medicine report *Medicare Laboratory Payment Policy, Now and in the Future* that "HCFA (Health Care Financing Administration, now known as the Centers for Medicare and Medicaid Services [CMS]) should review alternatives to the current system for coding outpatient clinical laboratory services for claims processing. More accurate, open, and timely coding processes for new technologies, as well as tests and services should be sought" (6). Thus, general familiarity with alternatives (e.g., International Classification of Diseases, Version 10, Procedure Coding System [ICD-10-PCS], based on an approach similar to the Logical Observation Identifier Names and Codes [LOINC]) is recommended (7). In addition, several payors have required the use of additional coding systems for molecular tests (termed DEX Z-codes) as a complement to CPT codes (8, 9).

The CPT System

Description

The CPT system, a proprietary product of the American Medical Association (AMA), is a listing of five-digit descriptors and numeric and alphanumeric identifiers that are used for documentation of services rendered. The system was first developed in 1966 and is currently in the 5th edition. The code lists are updated and published annually by a systematic process. The purpose of CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services that are critical to the communication between stakeholders about the care patients receive. These codes are used for financial and administrative purposes and to serve as a standard means of identifying and documenting services performed (10). These codes are multifunctional and serve as the basis for laboratory test order documentation and results, claim and invoice generation and billing, fee-for-service payment schedules, development of edits that assess the appropriateness of payment for the service, assessment of the productivity of laboratories in providing services, and utilization review and outcomes assessment in specific clinical situations (11). All aspects of effective financial management of the clinical laboratory begin with correct and complete coding for all services rendered (12). In essence, a "billable service" may be defined as one that is CPT codable and is often the basis for assessing laboratory productivity (13).

Types of CPT Codes

All generally accepted laboratory service codes, termed category I codes, are found in a specific pathology and laboratory section that includes both clinical laboratory and anatomic services (Table 31.1). Clinical laboratory services are further divided into discipline-specific subsections (e.g., chemistry, hematology, immunology, transfusion medicine, microbiology, molecular pathology). In addition, both technical testing services and professional, physician-provided services may be coded. In general, category I codes represent services that are performed by many healthcare professionals in multiple locations throughout the United States, that have received Food and Drug Administration clearance or approval, if required, and that have been shown to have clinical efficacy. Technical category I codes are of several types. Primary codes are those that denote a specific procedure. Add-on codes are those that are performed in addition to a primary code and are indicated by a "+" symbol or by the descriptor language "use in addition to." Organ- or disease-oriented panels represent AMA-approved and CMS-accepted test groupings that are coded as a single billable test procedure and are generally performed conveniently as such on automated instruments. Technical services are often subject to payment under a defined fee schedule based on CPT codes that is updated on a regular, generally annual basis.

Professional services are identified by specific CPT codes found in the anatomic pathology and cytology subsections and by several new, resource-defined codes in a clinical pathology consultation section. In addition, for a

本书版权归John Wiley & Sons Inc.所有

Table 31.1 Types of CPT-5 codes

Category I	All generally accepted laboratory service codes; found in the specific pathology and laboratory section (includes both clinical laboratory and anatomic services) Divided into specific subsections (e.g., molecular pathology, chemistry, hematology, immunology, transfusion medicine, microbiology) Represents services that are performed by many healthcare professionals in multiple locations throughout the United States, that have received Food and Drug Administration clearance or approval, if required, and that have been shown to have clinical efficacy
Category II	Developed for performance measurement tools Initially released in 2003, with annual updates Currently, there are no Category II codes that specifically address laboratory practices Use is optional and nonessential for correct coding
Category III	Implemented in 2001 Designed to be a temporary code set for procedures that represent emerging technologies not yet meeting the requirements for assignment of a category I code Retired after 5 years if not moved to Category I There have been several category III codes that describe laboratory procedures
MAAA	Implemented in 2015 Multianalyte Assay with Algorithmic Analysis codes consisting of multiple results from unique assays evaluated using a complex algorithmic process to generate a probability score May or may not be covered by payors
PLA	Implemented in 2016 to meet PAMA requirement for ADLT designation Proprietary Laboratory Analyses codes are proprietary assays performed by either a single laboratory or licensed specifically to other performing laboratories May or may not be covered by payors

few designated clinical laboratory codes requiring clinical interpretation, one may attach a two-digit modifier indicating that the code has both a technical and a professional component that may each be billed by different entities. Coding and billing for professional services are also generally subject to payment under a defined fee schedule that is developed through a resource-based relative value system (14).

Category II codes and category III codes represent newer components of the CPT system that were developed as a component of the CPT-5 (Table 31.1). Category II codes were developed as performance measurement tools and were initially released in 2003, with updates generated annually. They are designed to track best practices associated with specific clinical conditions and are thus similar conceptually to Healthplan Employer Data and Information Set (HEDIS) monitors, which are widely used by managed-care plans (15). However, at this point there are no category II codes that specifically address laboratory practices, although laboratory test use may be a component of the best practice algorithm associated with a specific category II code. At this time, the use of category II codes is optional and nonessential for correct coding.

Category III codes were implemented in 2001 and are designed to be a temporary code set for procedures that represent emerging technologies not yet meeting the requirements for assignment of a category I code. They are intended to be used to track utilization of these types of procedures and are updated biannually. It is possible that a category III code may eventually satisfy criteria for assignment of a category I code. However, from a correct-coding perspective, if a category III code is available, it must be used. In addition, if not assigned to a category I code in a 5-year period, these codes may be sundowned (i.e., retired). There have been several category III codes that describe laboratory procedures.

Molecular pathology coding (MolDx) has been expanded significantly in recent years commensurate with expanded clinical use. For infectious analytes, codes are found in the microbiology section and are both analyte and method specific, and include codes for syndromic multiplex assays based on the number of analytes. For noninfectious analytes (i.e., human genomic material), codes fall into several categories including analyte-specific Tier 1 codes, and resource-based Tier 2 codes, as well as genomic sequencing codes and other molecular multianalyte assays. It should also be noted that some payors require an additional code for molecular diagnostic tests, termed a DEX Z-code. This coding system was developed and is maintained by specific Medicare contractors, who also develop guidelines for coverage of these codes (16).

Two other relatively recent CPT categories of note are those termed Multianalyte Assays with Algorithmic Analysis (MAAA) and Proprietary Laboratory Analyses (PLA) codes. MAAAs usually consist of grouping of related tests which are correlated with a clinical outcome through a complex algorithmic process that generates a probability score. PLAs are assays, generally laboratory-developed tests (LDTs), that are owned and generally exclusively performed or distributed by a single laboratory.

Finally, it should be noted that the Protecting Access to Medicare Act of 2014 (17) also created two other terms for describing laboratory assays. Assays that are generally found on the Clinical Laboratory Fee Schedule (CLFS) with CPT or HCPCS codes are termed Clinical Diagnostic Laboratory Tests (CDLT), while assays that meet certain complex assay criteria and are often proprietary are termed Advanced Diagnostic Laboratory Tests (ADLTs). These assays may have an associated CPT PLA code.

本书版权归John Wiley & Sons Inc.所有

Modifiers

Modifiers are another important component of the CPT system. Modifiers are composed of two-digit numbers that are attached to a specific code prior to the billing process (Table 31.2) (18). They are "used to indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code." In laboratory medicine, there are several critical modifiers. The modifier -26 is used when a certain procedure is a combination of a physician component and a technical component. This modifier for "professional component" is only applicable in selected circumstances when the professional "interpretative" component is reported and billed separately.

Duplicate services of the same type on the same type of specimen from the same date of service are generally not reimbursed but may be appropriate if modified with -91 (repeat clinical diagnostic test performed on the same day to obtain subsequent reportable and clinically useful test values). However, this modifier may not be used when tests are rerun to confirm initial results (due to testing problems with specimens or equipment) or for any other reason when a normal, one-time, reportable result is all that is required.

Table 31.2 CPT and HCPCS modifiers commonly used in laboratory medicine

Modifier	Description
-26	Certain procedures are a combination of a physician component and a technical component; this modifier for "professional component" is applicable only in selected circumstances, usually involving inpatients, when the professional "interpretative" component is reported separately.
-91	Repeat clinical diagnostic test performed on the same patient, on the same type of specimen from the same date of service, to obtain subsequent reportable and clinically useful test values; this modifier may not be used when tests are rerun to confirm initial results (due to testing problems with specimens or equipment) or for any other reason when a normal, one-time reportable result is all that is required.
-59	This modifier (distinct procedural service) identifies distinct and separate multiple services of the same type on the same date of service that "are not normally reported together but are appropriate under the circumstances." This modifier generally refers to different encounters with the same patient or different anatomic sites.
-90	Used to indicate that a laboratory has referred a procedure it is billing to a reference laboratory. To use this code, laboratories must follow a 70–30 rule, which states that no more than 30% of total testing is referred out.
-QW	Used to indicate that a waived test has been performed in a properly CLIA-registered laboratory
-GA	Used to indicate that an Advance Beneficiary Notice has been obtained to indicate a test is unlikely to meet conditions for coverage

Modifier -59 (distinct procedural service) identifies distinct and separate multiple services of the same type on the same date of service that "are not normally reported together but are appropriate under the circumstances." This modifier generally refers to different encounters with the same patient or different anatomic sites. Modifier -59 is also used to report services that may be considered a component of another service but have been carried out in a distinctly unrelated fashion. The modifier is also not appropriate if a procedure is repeated due to analytical error or to confirm or verify a result.

Modifier -90 is used to indicate that a laboratory has referred a procedure it is billing to a reference laboratory. To use this code, laboratories must follow a "70-30" rule, which states that no more than 30% of total testing is referred out.

Laboratorians must also be familiar with a two-digit alpha character HCPCS modifier set to denote situations for which a CPT modifier does not exist (5). Modifier -QW is used to indicate that a procedure being performed in a Clinical Laboratory Improvement Amendments (CLIA) waived-status laboratory has received a waiver to be performed as such from the CLIA program. A series of very important HCPCS modifiers indicate the status of the acquisition of a "waiver of financial liability" (termed an advance beneficiary notice [ABN]) from the patient. The Medicare ABN must adhere to a specific format that should not be a component of a requisition. An ABN should be obtained whenever it is likely that a service does not meet Medicare payment rules and is therefore likely to be denied. Other third-party payors use notices modeled after the ABN to inform patients of their financial obligations for payment for coded services.

Use of modifier -GA is mandatory and indicates that Medicare is not likely to pay for a service and the patient has signed an ABN. Modifier -GZ is optional and indicates that Medicare is not likely to pay for a service, but the patient has not signed an ABN. Modifier -GY indicates that a service is statutorily excluded from payment and the patient has acknowledged financial responsibility by signing an ABN. Finally, -GX may be used when an ABN has been voluntarily issued for a noncovered service.

The Process for Change

Since laboratory procedures are constantly evolving, particularly with the emergence of new technology, it is necessary for the CPT system to undergo regular updates (Table 31.3). Updates, which add, delete, and modify existing codes, are issued annually after an extensive and systematic review process that begins with the submission of an AMA coding change request form by any individual, professional group, or corporation. Each request undergoes

本书版权归John Wiley & Sons Inc.所有

Table 31.3 Process and schedules for CPT code revisions

Timing	Action
18 months prior	Code changes are proposed
18 to 9 months prior	Proposals are reviewed by multiple AMA committees including: Health Care Professionals Advisory Committee AMA CPT Advisory Committee and subcommittees AMA CPT Editorial Panel
February prior	Final changes for the next calendar year are approved by CPT Editorial Panel
Summer prior	Early release of new codes for determination of reimbursement
October prior	Publication of the new edition for the upcoming year
1 January	Mandatory Medicare implementation of new codes
October–1 January	Time for action. Systematic efforts to verify codes, perform new cost analyses, update charge masters, change information systems, etc.

a complete review by AMA-appointed specialty committees, general CPT committees (the CPT Advisory Committee and the Health Care Professionals Advisory Committee), and ultimately the CPT Editorial Panel. The time frame to effect a change is usually 15 months or more, with new codes being released in midsummer since 2001 and the completely updated CPT manual released in hard copy by October prior to the January implementation date. Federal payors require use of new codes beginning in January. Other third-party payors generally follow the same timeline, but there may on occasion be disconnects. Note that PLA codes are issued more frequently on a quarterly basis, then included in the annual cumulative update.

HCPCS codes are also published annually but may be developed and issued any time with quarterly updates when it is deemed necessary to supplement the CPT system.

Procedure Coding Guidance: The Impact on Reimbursement

The selection and verification of CPT codes should be performed annually, coincident with the release of annual changes by the AMA. Correct coding is clearly the responsibility of the laboratory, in which the technical knowledge of the current procedures resides. Laboratorians must pay close attention to the narrative descriptors for the test procedures when selecting codes for use in documentation. Descriptors relate only to the procedure and do not reflect the reason for performing the test. Documenting why a test is performed generally requires an International Classification of Diseases-Clinical Modification (ICD-CM) code. Note that there are some exceptions to this duality of purpose. For example, many newly established preventative medicine screening benefits (e.g., HIV, HCV) require the use of newly established HCPCS codes that indicate both method and purpose (i.e., screening).

There is an established hierarchy for choice of CPT codes that places analyte first, followed by method, and then finally the use of a generic "not otherwise specified" code. If no match for the analyte and method can be found, then an "unlisted code" (usually ending with "-99") is available. However, as specificity of coding decreases, the probability that a code will not be reimbursed without submission of additional documentation increases. One should also review current HCPCS codes to determine if the procedure in question is described there. It is very important to ensure that one does not "unbundle codes," that is, select multiple individual codes rather than a comprehensive single code (e.g., when coding for panels). Further, the National Correct Coding Initiative (NCCI) directs that for federal payor programs, "multiple tests to identify the same analyte, marker, or infectious agent should not be reported separately." Keep in mind that the same guiding principles generally apply to other third-party payors.

Procedure Coding Alternatives

The CPT system is obviously firmly entrenched in laboratory management as the primary tool for procedure coding and subsequent billing of laboratory services. However, there are alternatives that may gain wider use at a future date. Foremost among these is a system known as the Logical Observation Identifiers Names and Codes (LOINC) system (19, 20). With input from a consortium of laboratories, information system vendors, hospitals, and academic institutions, the grant-supported Regenstrief Institute developed and maintains LOINC. LOINC is considered a universal laboratory language that is based on the systematic breakdown of the components of a service into more specific units, ultimately creating a highly standardized, typically seven-digit, number, with each possible result from a procedure being mapped to a specific code. The breakdowns take into consideration where the procedure was performed, the specific analyte type, the method, and the type of result. Unlike CPT, LOINC is publicly available and can be used with no license fee. It is widely used by commercial laboratories to track specific procedures from order to result.

The LOINC system formed the basis for the development of the CMS ICD-10-PCS laboratory coding system intended for use as an alternative to CPT (7). This system was developed by 3M under contract to the Health Care Financing Administration (now CMS), with substantial input from specialty professional groups. It was finalized and released in 1999 but has remained inactive, as CPT has continued to be used as the "official" procedure code set.

本书版权归John Wiley & Sons Inc.所有

Capitated Services

Beginning in the 1980s, a trend toward paying capitated, or predetermined, amounts for management of a specific disease or in a specific clinical circumstance rapidly emerged (21). This trend began with the Inpatient Prospective Payment System (IPPS) and the development of diagnosis-related groups (DRGs) under Medicare to classify reasons for hospitalization, where payment amounts were defined based not on the actual procedures performed but on the final diagnosis, while in other capitated payor plans, hospitalizations were paid for on a per-diem basis. Subsequently, this concept was extended by Medicare in 2014 to cover certain outpatient visits with an Outpatient Prospective Payment System (OPPS) and the development of ambulatory payment classifications (APCs). In addition, managed-care plans emerged that paid for all required services under terms like "per member per month," "per covered life," or "episode of care." Episodes of care may also be designated as Hierarchical Condition Categories (HCC) for risk-based reimbursement strategies (22). Finally, Medicare recognized special categories of patients for whom payments were similarly categorized by the condition or situation of the patient and not by a compilation of individual procedures. Examples may be found in payment for services to patients in skilled-nursing facilities (SNFs) or patients being treated in dialysis centers for end-stage renal disease (ESRD). Needless to say, other third-party payors find payment by these methods to be financially gratifying, and Medicare is seeking to move more patients into managed-care payment plans under Medicare Part C (termed Medicare Advantage).

In keeping with healthcare reform changes promoted through the Patient Protection and Affordable Care Act of 2010 (PPACA or ACA), the key concepts of coordinated, centralized, and cost-effective care coupled with prospective payment have been extended through accountable care organizations (ACOs). While it is not clear how pathology and laboratory medicine services will be most efficiently structured under ACOs, it is clear that the intent will be to provide services in the most cost-effective manner. While some models suggest that laboratory algorithms may be used to reduce unnecessary testing, other models suggest that laboratory testing may increase in some settings due to expansion of the use of laboratory tests used to screen for disease or disease precursors (23). Note that a definite trend is to try to find ways to standardize and minimize payment for services performed in a particular healthcare condition.

Under such capitated or prospective payment systems, laboratories may find themselves in the situation of representing financial liabilities rather than revenue generators. To balance this perception, it is extremely important for laboratories to develop mechanisms to document all work performed in a given clinical setting. Therefore, correct procedure coding is also a key to success in capitated payment situations. Knowledge of the exact amount of work performed per DRG or APC or other episode of care category allows one to justify the allocation of a specific proportion of the total payment to the laboratory. This also allows one to "carve out," or specifically exclude, unique high-cost niche test procedures from a contract. Thus, even in capitated payment situations, laboratorians should seek to code correctly for every laboratory procedure performed.

One additional code type of note that has been only rarely used in DRG payments is the New Technology Add-on Code (NTAP). These codes represent novel technologies that provide unique information for patient care that substantially improves management of patients and receives a separate reimbursement. A product's NTAP designation lasts for a maximum of 3 years for a given indication. The T2Bacteria panel from T2Biosytems is the only laboratory assay given an NTAP designation to date, but it is possible other novel technologies may achieve this designation (24).

Diagnosis Coding: Why Is the Service Being Performed?

As previously stated, the purpose of laboratory testing is to facilitate the management of a patient by a physician or other authorized healthcare provider. Thus, to accurately and completely document laboratory testing for both financial and clinical purposes, it is important to also document the reason(s) for performing the test. This too requires the use of a standardized and systematic approach if maximum information is to be readily obtained for administrative and financial purposes. The systems currently in use take into account the patient environment (e.g., inpatient versus outpatient) as well as the actual diagnosis, signs and symptoms, or other reason for the encounter. It is now both a statutory requirement for CMS as well as an almost uniformly accepted requirement for other third-party payors to provide diagnostic information for claim review prior to payment for services. The information is used to verify that a procedure is clinically necessary for payment purposes and to determine if it is clinically appropriate and useful for patient management in utilization review. It should also be acknowledged that provision of specific diagnostic information with each orderable and billable test is useful in the laboratory to ensure appropriate laboratory handling.

Inpatient Diagnosis Coding

For inpatient purposes, the DRG prospective payment system has already been mentioned. Effective in 1983, this system assigns a final diagnosis to each patient admitted to the hospital. The system was expanded in 2007 as a Medicare Severity DRG system (MS-DRG). Currently more than

本书版权归John Wiley & Sons Inc.所有

750 MS-DRGs have been defined that take into account clinical condition or reason for admission, medical responses, and presence or absence of complications. Each MS-DRG is weighted according to relative costs, inclusive of laboratory costs (although as already noted, the actual laboratory component is generally quite low), and payment schedules are published annually for a January implementation date. Supplemental secondary information termed Complications and Comorbidities (CC) and Major Complications or Comorbidities (MCC) may be used to justify a higher payment amount. DRGs are now used by many third-party payors to determine payment rates and are the primary basis for developing algorithms for cost-effective management of the condition specified by the DRG. These algorithms are known as "critical pathways," "clinical pathways," "care paths," or "order sets" and often include delineation of laboratory tests that should be performed as well as when testing is appropriate (25). Correct coding of these tests provides the laboratory a valuable means to track utilization as well as costs (26).

Such tracking has become very important recently, as the CMS has begun investigating why certain specific DRG or ICD-CM codes are consistently increasing both in relative proportion of total admissions and in percentage of total costs in a project dubbed "DRG or code creep" (27, 28). In addition, beginning in 2008 the CMS began to identify specific hospital-acquired conditions (HACs) that were not present on admission (POA) and are deemed preventable. In the case of the occurrence of a specified HAC, no additional reimbursement for the complication is made and for some conditions, higher rates of specific HACs may result in an across-the-board payment penalty. Documentation of both the HAC and the tests performed as a component of documenting the HAC will assume increasing importance as the list of HACs increases. Indeed, many HACs, especially infections, are identified based on laboratory testing and termed "Lab-ID" events (29).

One other critical parameter in coding for inpatient procedures pertains to the DRG payment window. At present, any procedure performed by an affiliated laboratory 3 days or less prior to an admission is deemed to be a component of the payment for the admission DRG that should not be billed separately. After discharge as well, any tests ordered on specimens collected during the hospital stay are considered as a component of the DRG assigned. However, it is still in the laboratory's best interest to continue to code for these procedures to document the actual work performed. Physician professional services are not included in the DRG but are billed separately.

Outpatient Diagnosis Coding

Medicare has initiated a prospective payment program for outpatient visits similar to the DRG system. As previously discussed, this prospective payment system is based on APCs. Like DRGs, diagnostic testing services are a component of the total payment made and it is again important for the laboratory to document the services performed.

Other Unique Patient Groups

Medicare also recognizes some unique patient groups for management and administrative purposes. For these groups, laboratory tests are frequently combined with other services for reimbursement. Examples include patients in ESRD clinics and patients in SNFs. If providing services to these groups, laboratories must be aware of the specific billing rules.

ICD-CM

For all of the above diagnosis groups, the actual payment is based on a complex formula that takes into account both the specific clinical conditions as well as the diagnostic procedures used. The primary coding system for documentation of the clinical conditions leading to a patient encounter is the ICD-CM (30). The ICD-CM used in the United States is currently the 10th edition (ICD-10-CM) but will likely be replaced in the future with a modified 11th edition (ICD-11-CM) approved by the World Health Organization (WHO) in 2022 (31). Basically, the ICD-CM system provides a mechanism to classify morbidity data for medical records, for medical care review, and for basic health and utilization statistics. It is the official CMS system for assigning codes for clinical conditions associated with consequent medical procedures, including laboratory testing. The system is maintained by a consortium of professional clinical medicine groups, professional medical record groups, the National Center for Health Statistics, the CMS, and the WHO. Updates are made on a quarterly basis and published for public use.

The ICD-CM is composed of a tabular numerical list of diagnoses, signs and symptoms, and clinical conditions or reasons for a physician encounter. The system includes both disease conditions or signs and symptoms, and preventative medical reasons for encounters. When a test is performed on a patient with signs, symptoms, or a specific diagnosis, the purpose is typically diagnostic or for monitoring progression. Such tests are often deemed "medically necessary" and are typically reimbursed. When a test is performed in the absence of signs, symptoms, or a specific diagnosis to identify patients with clinically silent disease, a disease precursor, or risk factors for a disease, it is referred to as a "screening test." Such tests may or may not be eligible for reimbursement (an issue further discussed in chapters 32 and 34). The system also allows coding for exposures and sources of external injury, as well as a classification system for surgical, diagnostic, and therapeutic procedures for inpatients. ICD-10-CM lists approximately 68,000

本书版权归John Wiley & Sons Inc.所有

codes, a significant expansion over the previous ICD-9-CM version with approximately 13,000 codes, and ICD-11 will offer additional specificity and some changes in coding structure.

SNOMED CT

An alternative clinical coding system developed by the College of American Pathologists is called SNOMED CT, which is an acronym for a comprehensive and precise "Systematized Nomenclature of Medicine Clinical Terminology." This system was developed in conjunction with the United Kingdom's National Health Service and is now maintained by the International Health Terminology Standards Development Organisation (IHTSDO). The system is designed to easily map to other diagnostic terminology systems, but it is unique in its ability to show expected and logical relationships between clinical conditions (32). For example, with the ICD-CM a foot ulcer may have diabetes as a contributing diagnosis, but with SNOMED, it is a diabetic foot ulcer. SNOMED CT is used primarily for clinical documentation in an electronic health record and is typically mapped to ICD-CM codes for reimbursement purposes (33). Like other major proprietary coding products, SNOMED CT is subject to regular updates and requires an appropriate license for use.

Service Location

The last major issue in correct coding is the assignment of credit for the work performed as well as credit for the revenue generated to the entity performing or billing the services. In most large laboratories, there are multiple departments performing testing, and it is necessary to assign each entity designated as an independent financial center a unique identifier for financial analysis purposes.

Role of CLIA and State Licensing

Under CLIA, each laboratory has a unique certificate number that validates its status as a billing entity for federal healthcare programs. Most other paying entities also use CLIA certification as an indicator of the operational validity of the laboratory. Laboratories may only bill for work performed that is compatible with the CLIA service level that they are assigned unless the laboratory is billing reference work properly modified as previously discussed with modifier -90 and not exceeding 30% of the test volume. Many states also have stringent facility licensing requirements, and in those states, a billing entity must also have a valid state licensure status. CLIA and some states require the facility certificate or license numbers to appear on claims.

Revenue Codes

Revenue codes comprise a system for categorizing and billing services that is recognized by CMS and most third-party payors. This system is maintained by the National Uniform Billing Committee of the American Hospital Association and is designed to standardize major revenue-producing centers in an institutional setting, particularly hospitals. For each test performed and charge code billed, the institution should determine which revenue code is most appropriate to assign credit. Both charge codes, which map to CPTs, and revenue codes, which map to actual testing location, must appear on claims.

Documentation of Codes

Two types of documents important in the billing and reimbursement process require the documentation of the codes assigned for procedures, diagnoses, and revenue centers appropriate to the testing. First is the requisition, which documents both the order and the diagnosis, and second is the claim form or invoice, which allows transmission of the bill for services to a payor. Healthcare providers frequently use coding data from both requisitions and claims in overall financial assessments of the laboratory operational efficiency. Therefore, it is important that the laboratory have a clear understanding of how each test name or procedure relates to specific coding documentation (34).

Requisition

Requisitions may be manual (hard copy) or, preferably, electronic but should be designed to facilitate the capture of all the required data for accurate processing of an order as well as effective processing of a claim or invoice. Standard elements include demographics of the patient, billing information, ordering provider contact and authenticity information (the unique provider identification number), date of service, and a menu of tests that may be ordered. The test menu should map to the institutional charge master (35) and to CPT coding information. It may also identify diagnostic information justifying payment by a third-party agency, and those tests requiring an ABN. Any test groupings not strictly defined as a panel by the AMA and any standard reflex protocols should also be clearly delineated. Of course, each orderable test should also have an easily accessible reference defining specimen requirements, methodology, clinical utility, and performance characteristics as well per CLIA.

Claims

Claims submitted to third-party payors are now generally required to be electronic, but they may occasionally be prepared as a manual process. It is also common to engage an independent contractor to perform procedure billings due to the complexity of the process, with many rules for ordering, billing, and reimbursement often being payor specific. However, claim forms have remarkable similarity in that they all depend on the use of standard coding nomenclature for patient identification, provider identification,

本书版权归John Wiley & Sons Inc.所有

laboratory identification, procedures including modifiers, diagnoses, and revenue centers. The forms used by the Medicare program serve as a model for the format of claims. Form UB-04 is the form currently required by Medicare for laboratory services submitted from healthcare institutions (e.g., hospitals), having replaced form UB-92, which was used until 2007. However, it should be noted that some nongovernment payors may still use form UB-92. Form CMS-1500 is required by Medicare Part B for claims submitted by physicians and independent laboratories to the contractor. Failure to complete all required information on either the requisition or the claim form may result in failure to be reimbursed for otherwise payable services.

Code Mapping

For optimal use of coding data obtained from requisitions and claims as a component of operational efficiency analysis, it is essential that there be a direct link between common elements in use. The common test names that appear on the requisition or in the electronic order entry system used by ordering providers should link to a specific CPT code or other code set such as LOINC and MolDx codes. Similarly, the common name and the related CPT code(s) should link to line items on the charge master for billing purposes. In addition, the laboratory service manual should have information on codes used, particularly for external clients who may independently bill for services. Since CPT codes are updated annually, a careful and well-documented annual review of all related documents is strongly encouraged.

SUMMARY

It is of paramount importance for the documentation of services rendered that laboratories employ the standardized coding systems recognized by payors. While use of each code set is subject to general guidelines provided by the maintaining entity, it is ultimately the responsibility of the laboratory to ensure that correct and complete coding has been done. This pertains particularly to assignment of correct CPT codes for delineation of services and verification that the codes map to the assigned charge code on a charge master, as well as the determination of circumstances in which appropriate modifiers may be used. Documentation of the ICD-CM code provided by the ordering provider is absolutely required for claim processing, although the primary responsibility of the laboratory is generally to ensure that claims are appropriately and correctly completed. However, diagnosis classification groups such as DRGs and APCs are assigned by medical record professionals within institutions, and revenue codes are assigned by appropriate finance personnel within an institution. Regardless of where the operational responsibility lies, there still remains a clear responsibility for the laboratory to understand the importance of these coding systems to their operations and to verify assignments of codes when appropriate. Without a doubt, all other aspects of billing and reimbursement processes begin with a solid understanding of and application of fundamental principles of correct and complete coding.

KEY POINTS

- It is mandatory that laboratories use standardized coding systems which are recognized by payors for documentation of services rendered.
- Although each procedure code set is subject to general guidelines, it is the responsibility of the laboratory to verify that correct and complete coding has been done.
- Documentation of the ICD-CM code provided by the ordering provider is required for claim processing and may occasionally be the responsibility of the laboratory.
- It is critical that the laboratory perform annual updates of procedure coding, including impact of changes on service manuals, requisitions and order entry systems, and charge masters.
- Test menu names should match or at least map to CPT codes to maximize reimbursement opportunities.
- It is the laboratory's responsibility to understand all aspects of correct and complete coding principles.

GLOSSARY

Accountable care organization (ACO) A coordinated care system in which providers are incentivized on the basis of outcomes rather than the number of services.

Adjudication (of a claim) Process by which payors review claims to determine payment or denial of payment

Advance beneficiary notice (ABN) A waiver of liability used by the provider to notify Medicare beneficiaries prior to receiving a service that it may not be a covered service and that they may have to assume financial responsibility, similar charges used by other payors.

Advanced diagnostic laboratory test (ADLT) A complex laboratory test category defined in PAMA and furnished by a single providing laboratory.

Ambulatory Payment Classification (APC) Classification system used by CMS for outpatient prospective bundled payment for certain categories and levels of outpatient services.

American Medical Association (AMA) A professional physician organization with responsibility for and control over the CPT system.

Analyte-specific reagent (ASR) An FDA-regulated category of reagents meeting specific quality requirements for clinical laboratories to use in developing laboratory-developed tests (LDTs). If the ASR is used in accordance with regulations and reasons for

本书版权归John Wiley & Sons Inc.所有

medical necessity are met, LDTs may be reimbursed at the discretion of a payor.

Assignment The fee Medicare or another third-party payor sets as approved for a covered medical service (also known as an approved charge). It may be less than the actual amount charged by a provider.

Balanced Budget Act of 1997 (BBA '97) Legislation with many far-reaching effects on Medicare, including reductions in payments to providers and a mandated negotiated rulemaking process to develop coverage determinations for laboratory services.

Balanced Budget Refinement Act of 1999 (BBRA '99) Legislation that addressed flawed policy and excessive payment reductions for federal healthcare programs resulting from BBA '97.

Bundling Placing multiple codes together in an orderable and AMA-approved panel.

Capitation A predetermined, fixed amount paid to providers in return for rendering a specified set of health services. The rate is generally established per person (per capita) enrolled in the health plan for a specified time frame (e.g., per month).

Carve out To exclude a test from a capitated contract and bill as an individual fee-for-service item.

Children's Health Insurance Program (CHIP) Federal program that provides low-cost health coverage to children in families that earn too much money to qualify for Medicaid. In some states, CHIP covers pregnant women.

Claim The manual or electronic document or invoice, which allows transmission of the bill for services to a payor.

Claims denial management A set of processes to enhance revenue by assessing and correcting reasons for payment denials.

Clinical Laboratory Fee Schedule (CLFS) An annually updated list of payment for services by CPT or HCPCS code (see also National limitation amount).

CMS-1500 The claim form authorized by the Centers for Medicare and Medicaid Services for filing Medicare Part B claims with contractors. Previously designated the HCFA-1500 (Health Care Financing Administration).

Contractors Centers for Medicare and Medicaid Services (CMS) primary third-party claims management entities who administer payments to facilities, physicians, and commercial laboratory providers according to national and local coverage determination policies; may also refer to other third-party payors.

Copay A fixed dollar amount or a percentage of a charge paid by the subscriber to the provider at the time of services.

Covered lives Population insured by a managed-care contract for prospective payment.

Cross-walking The process of setting a fee for a new code at same rate as that for another CPT code (or codes) deemed "equivalent" and to which it is "mapped."

Current Procedural Terminology (CPT) Proprietary service codes developed and maintained by the American Medical Association and required for filing claims and billing of Medicare and other third-party payors.

Denials Refusal of payment for a service by a third-party payor for a specific reason, often related to documentation deficiencies.

DEX Z-codes A unique five-character alpha-numeric code associated with certain molecular diagnostic (MDx) tests used by certain payers as an adjunct to nonspecific CPT codes. This code is assigned within the Palmetto GBA's DEX Diagnostics Exchange based on the uniqueness of each test being registered.

Diagnosis-related groups (DRGs) Classification system developed at Yale that defines more than 700 major diagnostic categories and places patients into case types based on the ICD-CM classifications. Substantially updated in 2007 as MS-DRG (Medicare severity adjusted) and may include additional documentation of Complications and Comorbidities (CC) or Major Complications and Comorbidities (MCC).

Downcode The use of a lower-reimbursed test to induce unnecessary utilization.

End-stage renal disease (ESRD) The term used for Medicare beneficiaries who have permanent kidney dysfunction requiring dialysis treatment.

Explanation of (medical) benefit form (EOB/EOMB) Provides reasons for denial of payment by a payor; known as a Medicare Summary Notice (MSN) for Medicare beneficiaries.

Fee-for-service A payment system in which individual service codes are reimbursed after service is rendered, also known as retrospective payment.

Gap filling The process of setting the fee for a new code deemed novel and not adequately described by an existing code. Payments are set by individual contractors based on existing charges, and these payments are then used to subsequently set a national limitation amount (NLA).

Healthcare Common Procedure Coding System (HCPCS) The code set recognized by federal and other third-party payors to describe medical, surgical, and diagnostic services. The CPT system is accepted as the HCPCS level 1 code set for laboratory and physician services.

Health Insurance Portability and Accountability Act of 1996 (HIPPA) Legislation that resulted in regulations to protect health insurance coverage for workers and their families when they change or lose their jobs, also required the Department of Health and Human Services to establish national standards for electronic healthcare transactions and national identifiers for providers, health plans, and employers and addresses the security and privacy of health data.

Health maintenance organization (HMO) A prospective payor for healthcare with emphasis on the prevention and early detection of disease and on continuity of care which generally offers a package of services; however, the choice of physician is frequently limited to those working within the HMO.

Health Technology Assessment (HTA) The systematic evaluation of properties, effects, and/or impacts of healthcare

本书版权归John Wiley & Sons Inc.所有

technology; includes medical, social, ethical, and economic dimensions, with the purpose to inform decision making in the health area including for laboratory medicine procedures.

Hospital-Acquired Condition Reduction Program (HACRP) A CMS initiative to reduce healthcare-associated conditions through an incentive and penalty payment program based on rates.

Health plan or health benefits plan Any organized system for delivering and reimbursing for healthcare services.

Healthcare Effectiveness and Data Information Set (HEDIS) Monitors for effectiveness of healthcare under various payor plans, generally measures compliance with evidence-based guidelines; developed and maintained by the National Committee for Quality Assurance (NCQA).

Hierarchical Condition Category (HCC) A risk-adjustment model for diagnosis coding originally designed to estimate future healthcare costs for patients.

Inherent reasonableness A CMS strategy used to arbitrarily reduce or increase a national limitation amount (NLA) deemed grossly excessive or grossly deficient.

Institute of Medicine (IOM) An independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public concerning health and science policy; known as the National Academy of Medicine (NAM) since 2015.

International Classification of Diseases, Clinical Modification A system for documenting clinical conditions and the reason for a patient encounter. The 9th edition (ICD-9-CM) was replaced by a substantially updated 10th edition (ICD-10-CM) in 2014 and will be replaced by ICD-11 in the near future.

International Classification of Diseases, Version 10, Procedure Coding System (ICD-10-PCS) Laboratory procedure coding system intended for use as an alternative to CPT; not currently in use.

Laboratory-developed test An assay developed by, validated by, and owned by a single laboratory; may use analyte-specific reagents (ASR) and be classified as a PLA or ADLT.

Laboratory Benefit Management Program (LBMP) A program administered through contracted entities which act as intermediaries between payors and providers to manage the use and costs of certain laboratory tests.

Logical Observation Identifier Names and Codes (LOINC) Considered a universal laboratory language that is based on the systematic breakdown of the components of a service into more specific units, ultimately creating a highly standardized, typically seven-digit, number, with each possible result from a procedure being mapped to a specific code. Unlike CPT, LOINC is publicly available and can be used with no license fee. It is widely used by commercial laboratories to track specific procedures from order to result.

Managed care A term used to refer to prepaid health plans (generally HMOs) that furnish care through a network of providers under a fixed budget to control costs.

Medicaid Healthcare plan established under Title XIX of the Social Security Act, which provides health insurance to the impoverished; the state and federal governments fund the program jointly.

Medicare Federally managed health insurance plan covering Americans over age 65, Americans under age 65 who have certain disabilities, and most patients with ESRD; established by a 1965 amendment to the Social Security Act. There are several distinct components (Parts A, B, C, and D).

Medical necessity The determination of ICD-CM codes for which a CPT code will be reimbursed as reasonable and necessary; if payment conditions are not met, considered "not medically necessary."

Medicare A/B contractor Designation for primary third-party contractors who administer Part A and Part B payments for covered services. Previously known as fiscal intermediaries for Part A and carriers for Part B claims management.

Medicare Modernization Act (MMA) Legislation considered to be one of the biggest overhauls of the Medicare program. It established prescription drug coverage and the modern Medicare Advantage (Part C) managed care program, among other provisions. It also created premium adjustments for low-income and wealthy beneficiaries.

Medicare Part A Federally managed health insurance plan covering Americans over age 65, Americans under age 65 who have certain disabilities, and most patients with end-stage renal disease (ESRD); established by a 1965 amendment to the Social Security Act. Part A covers part of hospitalization and skilled-nursing facility costs.

Medicare Part B Federally managed health insurance plan covering Americans over age 65, Americans under age 65 who have certain disabilities, and most patients with ESRD; established by a 1965 amendment to the Social Security Act. Part B provides supplementary coverage for medical services and supplies, including physician services, outpatient services, and certain home healthcare services, as well as diagnostic laboratory tests and services, X rays, and the purchase and rental of durable medical equipment.

Medicare Part C Federally managed health insurance plan covering Americans over age 65, Americans under age 65 who have certain disabilities, and most patients with ESRD; established by a 1965 amendment to the Social Security Act and revised under MMA. Part C provides coverage for medical services and supplies, including physician services, outpatient services, and certain home healthcare services, as well as diagnostic laboratory tests and services, X rays, and the purchase and rental of durable medical equipment under a managed-care plan.

Modifier Two-digit numbers (CPT) or letters (HCPCS) that are appended to a specific CPT code prior to the billing process. Modifiers are "used to indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code."

MolDx A program established in 2011 to identify and establish coverage and reimbursement for molecular diagnostic tests;

本书版权归John Wiley & Sons Inc.所有

consists of three components: test registration and ID assignment, application review, and coverage determination and reimbursement; tests are identified using a system of DEX Z-codes.

National Correct Coding Initiative (NCCI) Listings of CPT codes that should not be used simultaneously due to a determination that their use is not in accordance with the intended use; updated quarterly by a Medicare contractor. Procedure to procedure (PTP) edits fall into two major categories: comprehensive/component and mutually exclusive. Edits also indicate the code pairs in these edit categories for which a modifier (generally -59) may be appropriate. Additional edits included frequency edits (Medically Unlikely Edits [MUE]) and add-on code edits.

National Healthcare Safety Network (NHSN) A widely used healthcare-associated infection tracking system. NHSN provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections.

National limitation amount (NLA) The national fee cap for a particular test on the Medicare Clinical Laboratory Fee Schedule.

"Neg reg" Negotiated Rulemaking Committee for diagnostic clinical laboratory tests. The committee was charged with the development of national coverage determinations of medical necessity for select laboratory tests as a component of the Balanced Budget Act of 1997.

No Surprises Act Legislation that protects consumers with most types of private health insurance coverage against certain surprise medical bills signed into law in 2020, and with most protections in effect as of January 2022.

Payor mix Describes those entities that have fiscal responsibility for payment of services.

Physician Fee Schedule (PFS) An annually updated list of payment for services by CPT codes for physician professional services. Updates are made by a complex process including legislated adjustments and location considerations.

Physician office laboratory (POL) A laboratory operating out of a medical practice group office, generally providing rapid and CLIA-waived tests.

Point of service (POS) A type of insurance plan combining elements of both an HMO and a PPO. Referrals out of network are allowed but at some additional cost to the subscriber.

Preferred provider organization (PPO) A healthcare organization that negotiates set rates of reimbursement with participating healthcare providers for services to insured clients; a type of prospective payment system.

Price transparency regulations A CMS rule effective January 2021 that required hospitals to disclose pricing for covered services and items and revised July 2022 to include health plans; these entities must disclose rates paid by all categories of payors and patients.

Prior authorization A health plan cost-control process by which physicians and other healthcare providers must obtain advance approval from a health plan before a specific service is delivered to the patient to qualify for payment coverage; also known as precertification or prior approval.

Provider mix Describes those entities that actually perform and/or bill the services.

Prospective payment system Payment amounts are predetermined prior to the delivery of services. Profit results from care delivered at a total cost below the contract payment; loss results from care delivered at a total cost above the contract payment; also known as capitated payment.

Protecting Access to Medicare Act (PAMA) Legislation making significant changes to how Medicare pays for clinical diagnostic laboratory tests under the Clinical Laboratory Fee Schedule (CLFS). Effective 1 January 2018, the payment amount for most tests equals the weighted median of private payor rates submitted by applicable laboratories. Payment rates under the private payor rate-based CLFS are updated every 3 years.

Reflex test Second related test performed automatically when the initial test results are positive (e.g., identification and susceptibility tests on pathogens).

Regulation Legally binding rules developed to implement a statute.

Retrospective payment system Payment is rendered for specifically coded services after the service is rendered; also known as fee-for-service.

Saving Access to Laboratory Service Act (SALSA) Proposed bipartisan legislation intended to protect community and regional clinical laboratories from drastic reimbursement cuts under PAMA in 2023 and future years.

Secondary payor An additional healthcare plan that provides coverage on the balance after payment by the primary payor.

Skilled-nursing facility (SNF) A Medicare Part A benefit in defined circumstances for rehabilitative and extended care after a hospital discharge.

Stark and Anti-Kickback Laws Legislation passed governing physician referrals and payments that ensures that laboratories provide services to ordering providers without any evidence of inducement or kickback payment.

Statute A law passed by the U.S. Congress or a state legislature.

Substantially in excess of usual charges Under certain provisions of Section 1128 of the Social Security Act, the submission of claims for services substantially in excess of an entity's usual charges may result in the exclusion of that entity from participation in Medicare and Medicaid programs.

Third-party payor An entity, other than the person who received the medical care or services at issue (first party) and entity who provided the care or services (second party), responsible for the payment of medical expenses on behalf of a person through insurance, agreement, or contract.

TriCare A health plan for active duty military that draws on healthcare resources of the military system and a network of civilian healthcare professionals, institutions, pharmacies, and suppliers for healthcare services.

本书版权归John Wiley & Sons Inc.所有

Unbundling Coding individual tests rather than using an appropriate AMA-approved panel for payment by the CMS or another payor.

Upcoding Using a higher-paying code than justified to maximize reimbursement.

Veterans Affairs Medical Center (VAMC) The Veterans Health Administration (VHA) is the largest integrated healthcare system in the United States, providing care at over 1,000 facilities for inpatient and outpatient services of varying complexity to over 9 million veterans enrolled in the VA healthcare program.

REFERENCES

1. **Forsman RW**. 1996. Why is the laboratory an afterthought for managed care organizations? *Clin Chem* **42**:813–816.

2. **The Lewin Group**. 2008. Laboratory medicine. A national status report. https://www.lewin.com/content/dam/Lewin/Resources/Site_Sections/Publications/3993.pdf. Accessed 1 March 2023

3. **Melanson SEF**. 2014. Establishing benchmarks and metrics for utilization management. *Clin Chim Acta* **427**:127–130.

4. **American Medical Association**. 2023. *Current Procedural Terminology, Professional Edition*. AMA Press, Chicago, IL.

5. **Centers for Medicare & Medicaid Services**. 2023. UCPCS quarterly update. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. Accessed 1 March 2023.

6. **IOM**. 2000. *Medicare Laboratory Payment Policy Now and in the Future*. National Academy Press, Washington, DC.

7. **Averill RF**, **Mullin RL**, **Steinbeck BA**, **Goldfield NI**, **Grant TM**. 2001. Development of the ICD-10 procedure coding system (ICD-10-PCS). *Top Health Inf Manage* **21**:54–88.

8. **Santiago C**, **Chan-House K**.2022. Unwinding the Medicare MolDx (Molecular Diagnostic Services) Program. https://www.mcg.com/blog/2022/09/15/medicare-moldx-molecular-diagnostic-services-program/. Accessed 1 March 2023.

9. **Sireci AN**, **Patel JL**, **Joseph L**, **Hiemenz MC**, **Rosca OC**, **Caughron SK**, **Thibault-Sennett SA**, **Burke TL**, **Aisner DL**. 2020. Molecular pathology Economics 101: an overview of molecular diagnostics coding, coverage, and reimbursement. *J Mol Diagn* **22**:975–993.

10. **American Medical Association**. 2017. *Principles of CPT Coding*, 9th ed. AMA Press, Chicago, IL.

11. **Baselski V**, **Garcia L**, **Weissfeld A**. 2001. The ABCs of CPT coding in microbiology. *Clin Microbiol Newsl* **23**:37–42.

12. **Lorence DP**, **Ibrahim IA**. 2003. Benchmarking variation in coding accuracy across the United States. *J Health Care Finance* **29**:29–42.

13. **Valenstein PN**, **Souers R**, **Wilkinson DS**, **College of American Pathologists**. 2005. Staffing benchmarks for clinical laboratories: a College of American Pathologists Q-probes study of staffing at 151 institutions. *Arch Pathol Lab Med* **129**:467–473.

14. **MacMillan DH**, **Soderberg BL**, **Laposata M**. 2001. Regulations regarding reflexive testing and narrative interpretations in laboratory medicine. *Am J Clin Pathol* **116**(Suppl):S129–S132.

15. **Eddy DM**, **Pawlson LG**, **Schaaf D**, **Peskin B**, **Shcheprov A**, **Dziuba J**, **Bowman J**, **Eng B**. 2008. The potential effects of HEDIS performance measures on the quality of care. *Health Aff (Millwood)* **27**:1429–1441.

16. **Palmetto GBA**. 2023. Molecular diagnostic tests and Medicare. https://www.palmettogba.com/palmetto/moldxv2.nsf/DID/DPR5GEM991. Accessed 8 April 2023.

17. **Borden A**, **Showalter D**, **Storchan G**, **Hughes K**. 2015. The diagnosis for diagnostics: changes to Medicare payment and coverage of clinical laboratory tests. *Am J Manag Care* **21**(s12):SP407–SP408.

18. **American Medical Association**. 2020. *Coding with Modifiers*, 6th ed. AMA Press, Chicago, IL.

19. **McDonald CJ**, **Huff SM**, **Suico JG**, **Hill G**, **Leavelle D**, **Aller R**, **Forrey A**, **Mercer K**, **DeMoor G**, **Hook J**, **Williams W**, **Case J**, **Maloney P**. 2003. LOINC, a universal standard for identifying laboratory observations: a 5-year update. *Clin Chem* **49**:624–633.

20. **Khan AN**, **Griffith SP**, **Moore C**, **Russell D**, **Rosario AC Jr**, **Bertolli J**. 2006. Standardizing laboratory data by mapping to LOINC. *J Am Med Inform Assoc* **13**:353–355.

21. **Panning R**. 2014. Current status of clinical laboratory reimbursement. *Clin Lab Sci* **27**:119–126.

22. **Bronnert J**, **Kanter AS**, **Arco D**, **Cardwell M**.2020. Get the right reimbursement for high-risk patients. A proven strategy for managing Hierarchical Condition Categories in your HER. https://go.imohealth.com/CT-NA-200226-Reimbursement-HCCWP_01-ValueAbrv-LandingPage.html. Accessed 1 March 2023

23. **Evans M**. 2011. Test-driving an ACO. Norton Healthcare, Humana already seeing results in first year of pilot project. *Mod Healthc* **41**:38–41, 40–41

24. **LabPulse**. 2019. T2 Biosystems wins Medicare payment approval. https://www.labpulse.com/diseases/infectious/sepsis/article/15297955/t2-biosystems-wins-medicare-payment-approval. Accessed 1 March 2023.

25. **Schubart JR**, **Fowler CE**, **Donowitz GR**, **Connors AF Jr**. 2001. Algorithm-based decision rules to safely reduce laboratory test ordering. IFIP World Conference on Medical Informatics. 10:523–527.

26. **Malone B**. 2012. The future of lab utilization management. Are lab formularies the answer? *Clin Lab News* **38**:1, 6–7

27. **Steinwald B**, **Dummit LA**. 1989. Hospital case-mix change: sicker patients or DRG creep? *Health Aff (Millwood)* **8**:35–47.

28. **Liang F-W**, **Wang L-Y**, **Liu L-Y**, **Li CY**, **Lu T-H**. 2020. Physician code creep after the initiation of outpatient volume control program and implications for appropriate ICD-10-CM coding. *BMC Health Serv Res* **20**:127.

29. **Federal Register**. 2008. HACs Medicare program; changes to the hospital inpatient prospective payment systems and fiscal year 2009 rates; payments for graduate medical education in certain emergency situations; changes to disclosure of physician ownership in hospitals and physician self-referral rules; updates to the long-term care prospective payment system; updates to certain IPPS-excluded hospitals; and collection of information regarding financial relationships between hospitals. *Fed Regist* **73**(161):48434–49083.

30. **American Medical Association**. 2016. *Principles of ICD-10-CM Coding*, 4th ed. AMA Press, Chicago, IL.

31. **Orlousky H**. 2023. ICD-11: what to expect in the U.S.A. for the upcoming coding standard. https://www.rxnt.com/icd-11-what-to-

本书版权归John Wiley & Sons Inc.所有

expect-in-the-us-for-upcoming-coding-standard/. Accessed 1 March 2023.

32. **Brooch K**. 2003. AHIMA project offers insights into SNOWMED, ICD-9-CM mapping process. *J AHIMA* **74**:52–55.

33. **Bowman SE**. 2005. Coordination of SNOMED-CT and ICD-10: getting the most out of electronic health record systems. *Perspect Health Inf Manag*. (Spring):2005. https://library.ahima.org/doc?oid=106578. Accessed 15 October 2023.

34. **Federal Register**. 2001. Medicare program; negotiated rule-making: coverage and administrative policies for clinical diagnostic laboratory services. *Fed Regist* **66**(226):58788–58890.

35. **Kovar M**, **Shannon E**. 2011. Laboratory pricing: charge master risks and rewards. *N Perspect* **30**:15–17.

APPENDIX 31.1 General References and Resources

CPT manual, current professional edition, *current edition* (issued by AMA every October, effective 1 January)

CPT Changes: An Insider's View (current year) (AMA Press, Chicago, IL)

HCPCS Level II manual, current edition (issued every January and effective upon issuance)

ICD-10-CM manual (issued every October and effective upon issuance)

Medicare Clinical Laboratory Fee Schedule (issued every November and effective January 1)

Medicare Physician Fee Schedule (issued every November and effective January 1)

National Correct Coding Policy Manual, *Chapter X—Pathology and Laboratory Services,* current version (issued quarterly and effective upon issuance)

Codemap (subscription service available at http://www.codemap.com)

HCPro store (compliance and documentation subscription services available from HCPro at http://hcmarketplace.com/)

The Dark Report (*subscription service available at* https://www.darkintelligencegroup.com/)

Washington G2 Intelligence Reports (*subscription services available at* https://www.g2intelligence.com/)

本书版权归John Wiley & Sons Inc.所有

APPENDIX 31.2 Websites

American Medical Association (AMA) CPT resources

https://www.ama-assn.org/amaone/cpt-current-procedural-terminology (accessed 12 April 2023)

CPT Coding Resources

https://www.ama-assn.org/practice-management/cpt/need-coding-resources (accessed 12 April 2023)

Centers for Medicare and Medicaid Services

http://www.cms.gov (accessed 12 April 2023)

Appropriate Use Criteria

https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/appropriate-use-criteria-program (accessed 12 April 2023)

Clinical Laboratory Fee Schedule

https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinicallabfeesched (accessed 12 April 2023)

CMS Forms List

https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List (accessed 12 April 2023)

ICD-10 Resources

https://www.cms.gov/Medicare/Coding/ICD10 (accessed 12 April 2023)

Medicare Coverage Database.

https://www.cms.gov/medicare-coverage-database/search.aspx (accessed 12 April 2023)

Medicare Internet-Only Manual

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs (accessed 12 April 2023)

Medicare Learning Network (instructional resources for Medicare billing)

https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlngeninfo (accessed 12 April 2023)

MolDx

https://www.palmettogba.com/moldx (accessed 12 April 2023)

National Correct Coding Initiative Edits

https://www.cms.gov/medicare-medicaid-coordination/national-correct-coding-initiative-ncci/ncci-medicare (accessed 12 April 2023)

Protecting Access to Medicare Act (PAMA)

https://www.cms.gov/medicare/clinical-laboratory-fee-schedule/clfs-pama-educational-resources (accessed 12 April 2023)

Physician Fee Schedule

https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched (accessed 12 April 2023)

College of American Pathologists (CAP)

https://www.cap.org/ (accessed 12 April 2023)

Coding and Payment Resources

https://www.cap.org/member-resources/practice-management/coding-and-payment (accessed 12 April 2023)

Department of Justice

https://www.justice.gov/ (accessed 12 April 2023)

Healthcare Fraud Unit

https://www.justice.gov/criminal-fraud/health-care-fraud-unit (accessed 12 April 2023)

Government Accountability Office (GAO)

https://www.gao.gov/ (accessed 12 April 2023)

Food and Drug Administration (FDA)

https://www.fda.gov/ (accessed 12 April 2023)

Overview of IVD

https://www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation (accessed 12 April 2023)

Logical Observation Identifiers, Names, and Codes (LOINC)

https://loinc.org/ (accessed 12 April 2023)

National Academy of Medicine (previously Institute of Medicine)

https://nam.edu/ (accessed 12 April 2023)

Office of Inspector General (OIG)

https://oig.hhs.gov/ (accessed 12 April 2023)

Laboratory compliance program guidance

https://oig.hhs.gov/authorities/docs/cpglab.pdf (accessed 12 April 2023)

Special fraud alerts, bulletins and other guidance

https://oig.hhs.gov/compliance/alerts/ (accessed 12 April 2023)

SNOMED

https://www.snomed.org/ (accessed 12 April 2023)

United States Preventive Services Task Force (USPSTF)

https://www.uspreventiveservicestaskforce.org/uspstf/ (accessed 12 April 2023)

本书版权归John Wiley & Sons Inc.所有

32

Introduction
Interactions in the Billing Process
Provider Mix • Payor Mix
Terms of Coverage
Types of Services • Payment for Services
Logistics of the Billing Process
Claim versus Invoice Submission • Invoice Billing • Claim Billing
Fee-for-Service Arrangement Billing
Capitated Arrangement Billing
Value-Based Pay for Performance
SUMMARY
KEY POINTS
GLOSSARY AND APPENDIXES
REFERENCES

Approaches to Billing Laboratory Services

Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

OBJECTIVES

To illustrate the importance of hiring individuals well versed in all aspects of correct coding, including the rules and regulations

To discuss the importance of having a comprehensive information technology platform and software resources that ensure accuracy and completeness

To explain the need for laboratory personnel to be involved in the billing process and to maintain a close working relationship with members of the billing department

To explain the relationship between complete and accurate billing and the generation of sufficient income to continue to perform expected functions

Alas! How deeply painful is all payment!

George Gordon Noel, Lord Byron (1788–1824)

IT IS AN EXTREME UNDERSTATEMENT that the billing of clinical laboratory services is a tedious and complex process. The billing process can be said to be frequently overwhelming, rarely straightforward, always changing, and never easy. There are a number of variations among providing entities and among paying entities as well as in the types of tests being performed and actual process of how reimbursement for services is made (Table 32.1). The complexity is further increased by the sequential financial relationships between the patient requiring testing, the ordering provider making decisions about which tests to order, the laboratory interpreting the provider's order and verifying the appropriate mechanism to bill for services, and the payor, who reimburses an amount generally predetermined per contractual agreement and who may also deny payment based on criteria that are not always readily available or logical. The laboratory occupies a painful middle position in the entire process, where there is little or no input into the patient-physician process to effect appropriate test ordering and the acquisition of a properly executed requisition and advance beneficiary notice (ABN) if necessary. However, as the billing entity, the laboratory has total fiscal responsibility and complete financial liability for the procedures the physician may have ordered rightly or wrongly (1, 2).

An understanding of the specific requirements for billing laboratory services and a systematic approach for ensuring that the processes are carried out as specified are key to the financial success of a laboratory (3, 4). Underpayments by payors to providers under their payor agreements are a cause of significant lost revenue. Providers should devise a plan to make sure that payments made

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch32.

本书版权归John Wiley & Sons Inc.所有

to them are accurate and timely and adhere to other contractual obligations. Specific areas where underpayments are common include underfunding due to late payments, fee schedule changes that are contractually disallowed, miscalculation of performance or penalty-based adjustments, and errors in risk payment reconciliations, inappropriate denials or inappropriate downcoding of claims, or simply nonpayments (5). Claim denial management can enhance revenue, particularly in times of declining payment and increasing cost containment pressures (6). Proactive prevention strategies can minimize denials through accurately defining the scope of service, tracking causes for denials and nonpayments, and improving related processes.

Reader please note that the Glossary and Appendixes for the three chapters in this section are combined and provided at the end of chapter 31.

Interactions in the Billing Process

While the entire laboratory test process from test order to test result reporting to payment for services involves several categories of individuals, the actual billing process can be considered in terms of two main categories (Fig. 32.1). The "provider mix" describes those entities that actually perform and/or bill the services, and the "payor mix" describes those entities that have fiscal responsibility for payment for services.

Provider Mix

Since 1992, all laboratory providers must be registered under the Clinical Laboratory Improvement Amendments (CLIA) to provide the type of services they are billing for. CLIA classifies laboratories into four main categories: high-complexity laboratories (capable of providing all services), moderate-complexity laboratories (capable of performing procedures with slightly lower skill requirements and slightly lower patient risk), certificate-of-waiver laboratories (may perform only tests meeting "waived" criteria under CLIA and requiring minimal skill and carrying minimal risk to a patient), and provider-performed microscopy services (applying to only a select few microscopic procedures when performed by a physician or other authorized individual). When billing for laboratory services, the laboratory must have the appropriate CLIA status for the service being billed or the service will be subject to denial.

Laboratory services are provided in several types of facilities (Table 32.1). Hospital-based laboratory units and independent reference laboratories generally perform and bill more tests than the other categories. Hospital-based laboratories provide services for inpatients and often for outpatients in institutionally affiliated clinics and occasionally for nonaffiliated clinics termed "outreach business." Independent laboratories perform testing for a variety of clients, including hospitals, physicians, other healthcare providers, patients in areas where direct-access testing is allowed by law, and by contract for non-healthcare purposes (e.g., employee drug screens). With such a diverse clientele, independent laboratories are frequently quite high volume. Some develop and perform highly complex procedures not performed in a routine setting such as laboratory-developed tests (LDT). Physician office laboratories are generally established to provide convenient, rapid-response-type procedures, often CLIA-waived, that may impact immediate clinical decision making. The test mix is generally less complex in a physician office laboratory setting than in the other two settings. One final type of laboratory is the "niche" or "boutique" laboratory, which exists to provide services to specific groups of patients. For example, laboratories may focus on service to end-stage renal disease (ESRD) or skilled-nursing facility (SNF) patients. In other cases, the laboratories may focus on specific categories of diseases (e.g., cardiovascular, oncology) and perform LDTs, proprietary laboratory analyses, and advanced diagnostic laboratory tests in their test mix. Each type of laboratory must be prepared to follow the billing processes specified by all of the payors for which it is an approved provider. If the laboratory is not an approved provider, the laboratory services provided will be subject to denial.

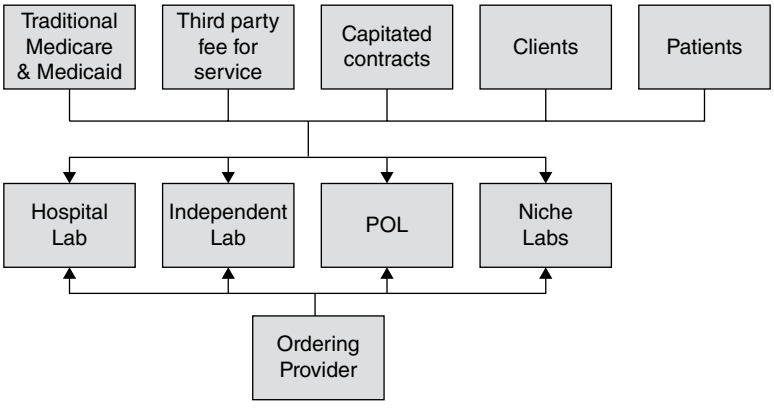


Figure 32.1 Payor-provider interactions in reimbursement. POL, physician office laboratory.

本书版权归John Wiley & Sons Inc.所有

Table 32.1 Variables in the billing process

Provider categories	Hospital laboratories	Associated with an accredited hospital provider; may perform services for inpatients, outpatients, or other clients
	Independent laboratories	Serve as an independent accredited laboratory service provider to hospitals, physicians, or other clients
	Physician office laboratories	Associated with a physician or practice group and accredited to perform designated laboratory services
Payor categories	Fee for service	This approach is retrospective; total amount to be billed is not known until services have been rendered; results in cumulative bill; fee schedule prospectively determined and accepted by provider and payor
	Capitated	This approach is prospective; payment amount established on some denominator (e.g., per member per month, per diagnosis-related group, or per ambulatory payment classification); payment based on average anticipated utilization in the denominator group
	Value based	May be either retrospective or prospective, and involves adjustment of payment based on defined performance metrics
Procedure categories	Diagnostic tests	Used to identify physiological abnormalities associated with disease
	Monitoring tests	Used to follow disease progression or response to therapy or to detect side effects of therapy
	Screening tests	Performed in the absence of signs, symptoms, complaints, injury, or personal history of a disease to discover potentially treatable or preventable diseases
	Tests requiring prior authorization	In some cases, there may be a requirement for prior authorization from the third-party payor for the test provided
Process categories	Invoice billing	Relatively simple process; can be based on fee-for-service or capitated payment schedule; amounts generally posted upon completion of testing; generated at some regular interval (e.g., weekly, monthly)
	Claim billing	Very complex; requires extensive and complete information; careful review prior to payment; payment often denied; need for rechecking all claim information and resubmission for payment

Payor Mix

The entities disbursing payment also fall into several categories. Federal payors include those in the Medicare program for senior and disabled citizens, a program that was initiated in 1965 as a result of the Social Security Act. Medicare pays for services that are "reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the malfunctioning of a malformed body member." Payments are made for either inpatient services, including services provided in an SNF through Part A, or outpatient services through Part B, with both parts administered through a Centers for Medicare and Medicaid Services (CMS) selected Medicare A/B contractor. In 1972 the Social Security Amendments added coverage to two additional high-risk groups—those disabled and receiving cash benefits from Social Security and individuals suffering from ESRD. As a result of the Balanced Budget Act of 1997, a new Part C program was established effective in 1999 and is also known as Medicare Advantage under the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). These managed-care programs offer coordinated and comprehensive care plans that combine and expand benefits of Parts A and B, but also generally restrict provider access. The Medicaid programs provide federal assistance to states for payment for healthcare for indigent citizens, and the Balanced Budget Act of 1997 created the State Children's Health Insurance Program (CHIP) to assist with the healthcare of children. These programs may also be configured as managed-care plans. Finally, individuals on active military duty may receive services through a TriCare provider plan and those with prior military service may obtain healthcare through Veterans Affairs Medical Centers (VAMC).

Federally funded healthcare plans are third-party payors; that is, payment for services provided by a healthcare provider to a patient is made by a contracted entity. Many other third-party payors render payment to laboratories as a component of a healthcare benefit plan, also referred to as simply a "healthplan" or as "health insurance." These plans require payment of regular premiums so that in the event of a high-cost or catastrophic illness, the third party will cover an agreed-upon percentage or fee for the services provided. There are multiple types of plans, including traditional indemnity, preferred provider organizations, point-of-service plans, and health maintenance organizations. Within the Medicare and Medicaid programs, there also exist variations comparable to those seen in the private sector. Adding to the complexity is the frequent presence of a "secondary payor," that is, another healthcare plan that provides coverage on the balance after payment by the primary payor. A generic third-party process is diagrammed in Figure 32.2.

Laboratories may also receive payments through contracts with specific physicians and other healthcare providers, who in turn bill third-party payors. These are

本书版权归John Wiley & Sons Inc.所有

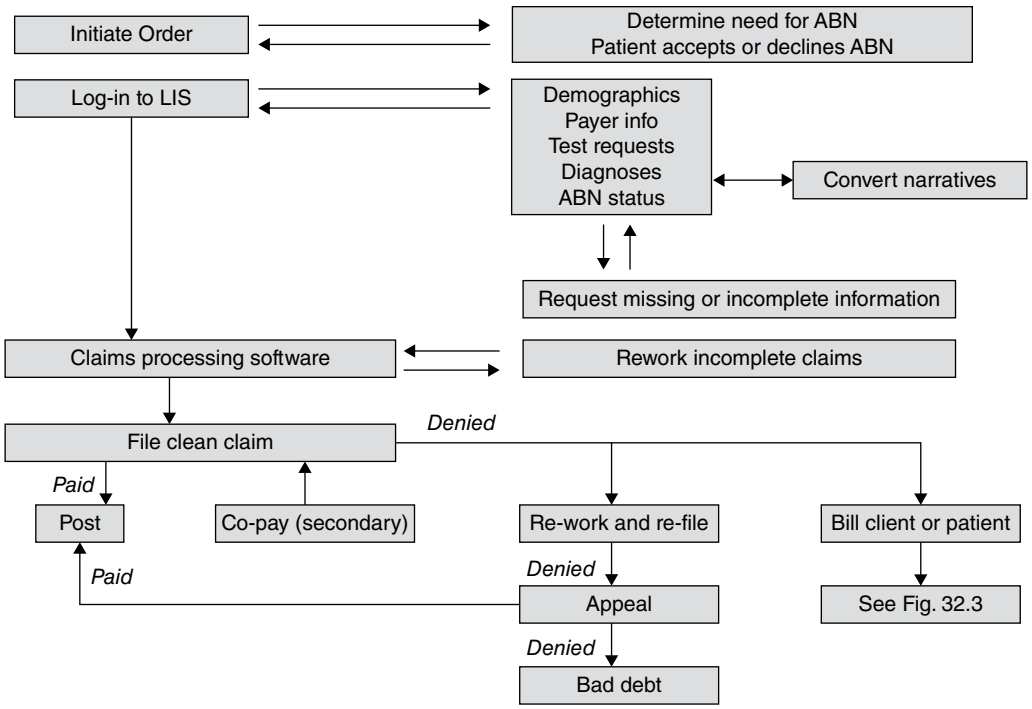


Figure 32.2 Generic billing flowchart: third-party. LIS, laboratory information system.

probably the easiest billing arrangements to execute. A generic client-bill process is diagrammed in Figure 32.3. It is important to note that this practice may be subject to "anti-mark-up" provisions for specific categories of tests pursuant to federal and state regulations. Laboratories are also required to bill patients who have no insurance coverage or have received a noncovered service, as well as in any circumstance in which the patient is expected to copay a percentage of the total bill. When a laboratory submits a bill for a specific service, whether through a third-party payor or to a contracted entity, or even to a patient directly, the terms of payment are termed "fee-for-service" or retrospective. That is, the laboratory is paid after designated services are rendered.

In some cases, laboratories do not directly bill or receive payment for individually defined services. Rather, a parent

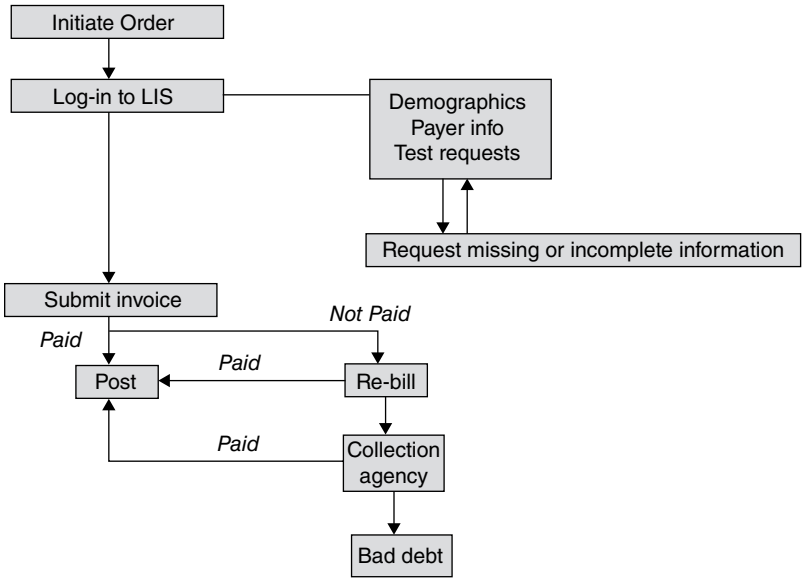


Figure 32.3 Generic billing flowchart: client or patient. LIS, laboratory information system.

本书版权归John Wiley & Sons Inc.所有

organization negotiates payment prospectively. These arrangements are termed capitated, and the payment is made at a set amount on a basis other than individual test. For example, payments may be per diem or per individual according to contractual terms. Medicare DRG (diagnosis-related group) payments are an example of capitated payment for hospitalizations, APC (ambulatory payment classification) payments are for hospital outpatient services, and more recently, ACO (accountable care organization) arrangements may be globally constructed to encompass all aspects of laboratory medicine. In these kinds of arrangements, it is critical that the laboratory have a system in place to completely document services performed so that accurate capitated payment terms can be negotiated that include consideration of expected laboratory services.

One final recent contributor to payment should be noted; that is value-based payment. In these models, whether retrospective or prospective, the payor requires that certain metrics for performance be achieved in order to receive full compensation. Payments may be adjusted by a specified percentage either upward or downward based on performance and will be discussed in more detail in chapter 36. These arrangements can be considered "introspective," that is, based on examination and review of data. A summary of these three general payment processes is seen in Table 32.1.

Terms of Coverage

Each individual payor sets criteria for payment for services (both which types and under what conditions). Further, each payor is intimately involved in the determination of the actual payment amount.

Types of Services

Several general categories of laboratory services are performed based on clinical utility, and payors vary in whether these services will be covered (Table 32.1). The terms "covered services" and "noncovered services" are used to categorize whether a specific type of service will be covered. Diagnostic tests assist in the determination of an etiology for a specific disease or clinical condition. They are almost always covered by third-party payors, although there may be restrictions on which specific tests may be used. In addition, there may be restrictions on when a test may be used based on diagnosis or clinical condition. This type of restriction is generally known as "medical necessity." Monitoring tests are used to follow disease progression or response to therapy or to detect side effects of a therapy. Monitoring tests are generally covered when the therapy is also covered and may also be subject to restrictions. Screening tests are performed in the absence of signs, symptoms, complaints, injury, or personal history of a disease to discover potentially treatable or preventable diseases. They may or may not be covered by a third-party payor, depending on the particular health plan coverage conditions. A classic example of noncoverage of screening is in the Medicare program, which by historical interpretation of statute allows payment only for "treatment of illness or injury" and not for "screening." For all test types, there may be frequency restrictions that limit the number of times a test may be performed in a given period. In addition, in some cases, there may be a requirement for "prior authorization" for the test service provided. This is, in essence, the obtaining of approval of payment for the service by the third-party payor. If a particular test is deemed noncovered, then the patient generally assumes financial liability for the service if there has been prior notification and acceptance of such.

One new trend to be aware of is the use of a laboratory benefit management program (7). Similar to pharmacy benefit programs, an independent contracted entity may both negotiate payments and define indications for testing, Such entities are also known as health technology assessment (HTA) bodies (8), but the aim is almost always to limit coverage circumstances that meet generally accepted standards of care and to limit payment to the lowest amount possible to effect savings in total healthcare costs.

Payment for Services

There are two general approaches to payment for healthcare services, including laboratory services (Table 32.1). The traditional approach and the one most commonly employed is based on a fee-for-service strategy. This approach is retrospective in that the total amount to be billed is not known until services have been rendered and a cumulative bill is generated. However, the fee schedule used for billing has been prospectively determined and accepted by both the provider and the payor. Traditional federal payment programs are based on a fee schedule set annually by a specific formula. Other payors generally develop fee schedules after negotiation with providers. Fee schedules may vary considerably based on considerations related to the "cost of doing business" with a particular payor.

The alternative approach is one based on capitation. This approach is prospective in that a payment amount has been established based on a designated denominator such as per member per month, per DRG or APC, or per some other patient-related parameter. The payment is based on average anticipated utilization of healthcare services by patients in the denominator group and should include specific consideration of laboratory medicine services. For select high-cost, esoteric laboratory tests, the parent organization may choose to "carve out," or exclude, the test from the capitated payment and bill separately. A Medicare

本书版权归John Wiley & Sons Inc.所有

demonstration project for certain genetic tests was recently undertaken to assess impact of this kind of approach. Payment for outpatient services on a capitated basis is not currently common in office-based laboratory medicine although the approach is now used for hospital-based outpatient services using APCs (9). However, in the inpatient population, in SNFs, and in other specialty niches (e.g., ESRD facilities), both Medicare and other payors have moved toward a prospective payment system. In addition, a recent move toward the establishment of ACOs that will negotiate payment for complete healthcare services for a covered population suggests a move toward greater use of capitated systems. Thus, the laboratory needs to be familiar with both approaches.

Note that either payment system may also have a "value-based" component. That is, payment may be adjusted up or down based on established and expected performance metrics. These systems are usually based on clinical performance metrics but may include some laboratory metrics and may have a downstream impact on laboratories within a healthcare system. One example of such an approach is in the use of National Healthcare Safety Network metrics for hospital-acquired infections (HAI) which rely on laboratory data in their definitions (termed "Lab-ID events"). These HAI rates are in turn used in the Hospital-Acquired Condition Reduction Program (HACRP) to determine if an overall reduction in Medicare payments will be applied (10). Laboratories should be aware of these types of payment arrangements and the impact of laboratory testing on overall reimbursement.

Logistics of the Billing Process

The actual billing process is obviously quite complex considering all of the variations in possible interactions between providers, payors, and patients. There are numerous fee schedules, various billing arrangements, multiple payors, diverse manual and electronic forms, variable coverage conditions, and payor-specific rules. Nonetheless, one can outline and compare the general processes involved in billing for laboratory services.

Claim versus Invoice Submission

Claims for payment are generated for submission to third-party payors, while invoices are generated for contractual payment by clients or by patients (Table 32.1). Claims are typically submitted electronically, although the same information may be submitted on a manual claim form. Claims are very complex and require that a great deal of information be accurately and completely provided (11). This includes date of service, correct codes for services and diagnosis codes, complete patient demographic information, complete payor information, and an ABN specific to each service likely to be denied. It is also possible to outsource billing activities to an independent entity that is familiar with the various rules and regulations pertaining to major payors. Invoices may also be generated manually or electronically; however, invoices are much less complex, generally including only the date of service, patient demographics, and types of services. Thus, billing costs are generally much lower for non-third-party billings.

Invoice Billing

Invoice billing is a relatively simple process (Fig. 32.3). After an order is placed and logged in to a laboratory information system, the tests ordered are performed and result reports are generated in the appropriate laboratory department, and a cumulative invoice is generated at some regular interval (e.g., weekly, monthly). The invoice may be based on either a fee-for-service or capitated payment schedule. It may on occasion be necessary to verify information pertaining to an order from the requisition, but the overall process is relatively straightforward. The billed entity either pays or does not pay in the expected time frame. Nonpayment generally results in one or more repeat billings and, eventually, action by a collection agency. The amounts due are generally posted upon completion of testing but on occasion may be generated at the time of order. This, however, carries the risk of billing for tests that may not have been completed and requires that a system be in place to issue credits whenever necessary.

Claim Billing

The entire claim process is quite complex, requiring multiple steps conducted over a lengthy period. It also begins with the generation of an order. However, at the time of test order, it is necessary to compare the tests ordered to the diagnoses given to determine if a waiver of financial responsibility (ABN) is required. If it is required, an attempt may be made to contact the ordering provider for additional relevant diagnostic information, but documentation of the attempt must be signed by the patient and maintained on file. Test orders are then logged in the laboratory information system, and samples are routed to the appropriate laboratory for testing and result reporting. During log-in, if any information critical to processing the order for testing or billing is missing, it is again necessary for the laboratory to contact the ordering provider to seek additional documentation. As in invoice situations, a bill for service may be posted at the time of log-in or at the time of result reporting, but if the former is done, there must be a system in place to accurately issue credits when necessary.

Claims are generally processed according to date of service, so multiple services may be submitted on a single claim. However, the ABN, if required, must be both date

本书版权归John Wiley & Sons Inc.所有

and test specific. It is also necessary to attach appropriate modifiers to any test code requiring one for payment.

After preparation, each claim is generally subjected to a review using "claims processing software" (12). This kind of review evaluates each claim to determine if all of the information required is complete and accurate. Importantly, this review also assesses whether a claim is likely to be covered by the particular payor (13). If not, then once again, calls are made to the ordering provider to attempt to obtain appropriate documentation. Once "clean," the claim is actually filed with the payor.

After filing, there are several possible outcomes. In the best case, the claim is paid and the funds are posted to an appropriate account. If the claim is denied, the denial documentation may be reevaluated to ensure that everything was in order, and if not, the claim must be corrected and refiled (14). The process by which payors review a claim to determine payment or denial is termed "adjudication." Denial documentation is generally sent to both the laboratory and the patient as an explanation of benefit (EOB) or explanation of medical benefit (EOMB) form. Denials are coded with a generic description outlining the reason(s) for the denial. Careful review of the EOBs can greatly assist in correction of documentation to subsequently obtain payment. If upon review it is determined that payment was appropriate, it is also possible to initiate an appeal for review and reconsideration by the payor.

Alternatively, a new claim or a claim for remaining amounts may be filed with a secondary payor by following the same general pattern. If no payment is forthcoming from any payor, and an ABN or other acceptance of liability is on file, the patient may be billed. It is also necessary to bill the patient in any case in which a copay is part of the process. In cases in which a provider has consistently failed to provide essential information, a laboratory may choose to bill the errant provider. Once a patient or client is billed, the process follows the pathway described for the invoice process. Certainly, the billing format and accuracy can play a large role in both client and patient satisfaction and understanding.

Fee-for-Service Arrangement Billing

The most straightforward billing arrangement is a fee-for-service arrangement. Appropriately coded procedures are billed to a payor based on a predetermined fee schedule. The procedures may be billed upon order or after completion, although the latter approach is less prone to corrections when a test is not performed for a variety of reasons including inappropriate samples or invalid results. These arrangements are considered retrospective in that the billing follows the order and testing, and the total payment amount is not predetermined. While billing is straightforward, there may be restrictions on payment that complicate the process such as "medical necessity" determinations (discussed in chapter 34).

Capitated Arrangement Billing

In a capitated arrangement with a laboratory, billing and payment are operationally similar to invoice billing. Terms and conditions, frequency, and amounts are, of course, defined contractually. If a parent healthcare organization is the billing provider, the laboratory is not directly involved in billing or receipt of payment. Under these conditions, the laboratory is frequently seen as a cost center rather than a revenue center. Thus, it is very important for laboratory managers to maintain accurate and complete documentation of the laboratory service activity, both for utilization review and for future contract negotiations. These arrangements are considered prospective in that the total payment amount is predetermined and not based on specific orders placed by a provider.

Value-Based Pay for Performance

While not strictly an operational issue, laboratorians should take note of an increasing trend toward use of pay-for-performance monitors in adjustment of reimbursement amounts. Laboratories already generate utilization and diagnostic data of value for assessing patient outcomes in specified disease conditions, and these data influence capitated payments. For example, reduced payment by Medicare for complications resulting from hospital-acquired conditions defined in part through laboratory results are already a reality. It is highly likely that specific laboratory payments may similarly be linked to performance data. These arrangements can be considered "introspective" in that careful and complete assessment of utilization may affect total payment by a payor.

SUMMARY

With the complexity of the billing process, it is no wonder that in many laboratories, the billing department has undergone rapid expansion in the number of employees. The billing department must employ individuals who are well versed in all aspects of correct coding and who are knowledgeable about the myriad rules and regulations pertaining to each payor. The billing processes are so complex that it is virtually impossible to develop and submit claims and receive payment without a sound information technology platform and software resources that ensure accuracy and completeness of the process. It has also led to a trend to outsource billing functions to an experienced and knowledgeable contracted entity.

本书版权归John Wiley & Sons Inc.所有

However, it is also critical that laboratorians remain involved in the billing process and maintain a close working relationship with members of the billing department. Extensive technical expertise is required to ensure that test procedures are coded correctly, as well as to determine that best practices for laboratory medicine are being followed. For clinical laboratories, the key to survival is in complete and accurate billing for all services performed so that timely and comprehensive payment can be made for those services. Regardless of the corporate structure of the laboratory one practices in, the generation of sufficient income to continue to perform expected functions is absolutely essential.

KEY POINTS

- It is mandatory that laboratories hire personnel who are well versed in all aspects of correct coding, including the rules and regulations.
- It is almost impossible to develop and submit claims and receive payment without adequate information technology systems (platforms and software).
- Select laboratory personnel must be involved in the billing process and work closely with members of the billing department.
- Complete and accurate billing is required to generate sufficient income for laboratory operations to continue.

GLOSSARY AND APPENDIXES

Reader please note that the Glossary and Appendixes for the three chapters in this section are combined and provided at the end of chapter 31.

REFERENCES

1. **The Lewin Group**. 2008. Laboratory medicine. A national status report. https://www.lewin.com/content/dam/Lewin/Resources/Site_Sections/Publications/3993.pdf. Accessed 1 March 2023.

2. **IOM**. 2000. *Medicare Laboratory Payment Policy Now and in the Future*. National Academy Press, Washington, DC.

3. **Longberry J**. 2009. The clinical laboratory fee schedule yesterday, today, tomorrow. *Clin Lab Sci* **22**:99–104.

4. **Panning R**. 2014. Current status of clinical laboratory reimbursement. *Clin Lab Sci* **27**:119–126.

5. **Welter T**, **Stevenson P**. 2001. Calculating five types of typical underpayments. *Healthc Financ Manage* **55**:46–50.

6. **Alwell M**. 2003. Stem revenue losses with effective CDM management. *Healthc Financ Manage* **57**:84–88.

7. **Cohen D**, **Hoffman P**. 2003. When putting patients first fits the bill. *Healthc Financ Manage* **57**:90–96.

8. **Seifert O**. 2022. HTA bodies: What they are and why do they matter? https://www.evidencebaseonline.com/hta-bodies-what-are-they-and-why-do-they-matter/. Accessed 1 March 2023.

9. **Wolf P**. 2001. Charge-process strategies for outpatient prospective payment. *Healthc Financ Manage* **55**:58–61.

10. **CMS**. 2023. Hospital-acquired condition reduction program. https://www.cms.gov/medicare/quality/value-based-programs/hospital-acquired-conditions. Accessed 15 October 2023.

11. **Smith-Shoemake MA**. 2002. Solving the claims conundrum. *Manag Care Q* **10**:13–14.

12. **Segal MJ**, **Morris S**, **Rubin JM**. 2002. Automated claim and payment verification. *J Med Pract Manage* **17**:297–301.

13. **Adams DL**, **Norman H**, **Burroughs VJ**. 2002. Addressing medical coding and billing part II: a strategy for achieving compliance. A risk management approach for reducing coding and billing errors. *J Natl Med Assoc* **94**:430–447.

14. **Hodges J**. 2002. Effective claims denial management enhances revenue. *Healthc Financ Manage* **56**:40–50.

本书版权归John Wiley & Sons Inc.所有

33

Introduction
Calculating Costs and Charges
Determining Costs • Setting Charges
Determining Payment Amounts
Fee Schedules • Medicare Clinical Laboratory Fee Schedule • Fee Setting for New Codes on the CLFS • The Medicare Physician Fee Schedule • Other Fee Schedules • Capitated Payments
Keys to Success in Reimbursement
Retrospective Payment • Prospective Payment • Value-Based Payment
SUMMARY
KEY POINTS
GLOSSARY AND APPENDIXES
REFERENCES

Charges and Fees for Laboratory Services

Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

OBJECTIVES

To discuss the four key concepts related to payment for laboratory services

To explain the relationship between charges and fee schedules and a reasonable profit margin

To describe the uses for profits and how they relate to generating returns on investments

To describe the following terms: market competitive and value-added services

To discuss appropriate ways to avoid the appearance of kickbacks and how this relates to compliance

Put money in thy purse.

William Shakespeare (1564–1616)

THE ULTIMATE GOAL IN THE PROVISION OF LABORATORY SERVICES is to make certain that information is delivered to ordering healthcare providers in a timely manner that ensures that quality is maintained, costs are minimized, and clinical relevance is established. At the same time, it is paramount to make sure that the laboratory does not lose money in doing so. This concept applies regardless of the corporate structure. It has been said, "For-profit entities exist to make money, and not-for-profit entities make money to exist, but both need to make money to survive." To make money in the laboratory business, it is critical that one establish charges that at least cover total costs and control expenditures such that low-paying fee schedules do not put the laboratory at risk for significant loss, and to ensure that a reasonable profit margin is achieved to support and sustain continued laboratory development. At the same time, one must understand that the opposing goal of a payor is to control payments.

Reader please note that the Glossary and Appendixes for the three chapters in this section are combined and provided at the end of chapter 31.

Calculating Costs and Charges

Determining Costs

The responsibility for cost analysis of individual laboratory procedures rests primarily with the laboratorian (1–3). Chapters in section V present an in-depth look at the process of cost accounting in the clinical laboratory. However, for

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch33.

本书版权归John Wiley & Sons Inc.所有

purposes of determining a charge structure, it is critical to have a clear understanding of the total costs of a procedure (4). A commonly used measure for this purpose is the "cost per reportable test." In general, an "orderable and reportable test" will map to a specific Current Procedural Terminology (CPT) code or codes, as well as to the institutional charge code for accounting purposes. The cost per reportable test is a composite of all related costs. These include the obvious costs such as average direct costs (e.g., reagents, equipment), including labor, and indirect costs, including overhead and support services (e.g., housekeeping, couriers, billing, customer service, marketing), but they also include hidden costs such as quality control, calibration, repeats, dilutions, and wastage. The cost per reportable test is considered to be a parameter that allows "apples to apples" comparisons between methods (inter-assay) and between laboratories (intra-assay).

In addition, the cost per reportable test is a useful tool for setting charges such that the laboratory maintains an appropriate profit margin. The break-even point is the point at which net income equals total costs. Net income takes into account actual payment for services and deducts actual costs as well as "bad debt," that is, the amount that is not reimbursed by any potential payor. Obviously, the goal is to do better than break even since profits are essential to support business development. To be profitable, one must have a clear understanding of both total costs per reportable test as well as expected net income.

Setting Charges

A number of general principles guide the process of setting a charge (5). One must consider the actual total costs and the expected reimbursement, so that one can at least meet and potentially exceed the break-even point. In general, it is never good business to price any service below cost, and in fact, this practice could be viewed as an inducement for ordering providers to submit federally reimbursed testing to a particular laboratory. On the other hand, one cannot charge federal payors "substantially in excess of usual charges," potentially leading to a conclusion that these payors are being overcharged (6). At the same time, one must review the market situation and ensure that charges are comparable to those of competitors unless the service offered has a quantifiable value-added component. In some market settings, laboratories may identify tests that are high volume and offer them at a charge below cost (termed a "loss leader"). At the same time, more esoteric, high-cost procedures with lower utilization may be offered with a substantial profit margin to make up the difference (termed "pull-through"). In addition, the billing simplicity of a contractual arrangement in which clients or patients are billed directly is considered a justification for offering deep discounts since billing costs are substantially lower and the percentage of services paid for is significantly higher.

However, the entire area of discounts and multiple fee schedules has come under intense scrutiny in recent years, and this practice needs to be carefully evaluated for providers, particularly those doing business with federal payors. Although it is a longstanding interpretation of Medicare law that one cannot charge federal payors "substantially in excess of usual charges," exactly what "substantially in excess" means is not well established, although the Office of Inspector General (OIG) has proposed a level of 120% greater than a usual charge for the same item or service for any payor. "Usual charge" is generally defined as either the average or median of charges to all parties for the most recent 1-year period (6). In addition, a previous OIG advisory opinion noted that discount arrangements may be reviewed to determine "whether the discount on the PPS-covered services makes business sense standing alone without reference to any other business the provider may receive" (7). Legislation known as the Stark and Anti-Kickback Laws is designed to ensure that laboratories provide services to ordering providers without any evidence of inducement or kickback. Thus, determination of charges currently has both financial and compliance implications.

Recently, there has been an increased emphasis on price transparency, and new Centers for Medicare and Medicaid Services (CMS) rules require that hospitals publish prices that a patient is expected to pay (8). Unfortunately, few hospitals have complied with this requirement (9) and few patients know the rule exists (10). However, one can expect that consumer interest in pricing will continue to grow, and issues of price transparency have the potential to impact both utilization and reimbursement (11). In addition, the recent No Surprises Act (12) may further control excess charges for healthcare services including laboratory services. This act requires that patients receive good faith estimates for services that may not be covered by a payor in certain settings and establishes a certified independent dispute resolution (CIDR) process for receipt of a bill that is substantially greater than the estimate received (13). Such protections are already in place for many government payors. It is likely that this may apply to relatively large charges associated with newer molecular technologies but could equally apply to routine services as well since charges may vary considerably based on payor (14). The laboratory should be aware of these transparency and payment rules in establishing charges (15).

Determining Payment Amounts

The amount of payment made for laboratory services may be based on one of two general categories. A fee schedule represents one category, although payment amounts typically vary based on payor. Actual provider charges may apply to some payors, while payor-defined fee schedules

本书版权归John Wiley & Sons Inc.所有

may be the basis for others. In capitated payment agreements, the payment takes the form of a negotiated agreement for a specified level or category of service, often based on diagnosis, clinical condition, or episode of care.

Fee Schedules

Counter to attempts to develop rational charges based on real costs and net income is the concept of payor-established fee schedules. Many payors will arbitrarily establish a fee schedule for defined services, and it is the laboratory's responsibility to determine whether to do business with that particular payor. Fee schedules are generally loosely based on charges although often set at a percentage substantially lower than actual charges. In addition, fee schedules may vary considerably by payor. The quintessential example of payment according to fee schedule is the Medicare Part B Clinical Laboratory Fee Schedule (CLFS).

Medicare Clinical Laboratory Fee Schedule

Medicare has historically paid for technical clinical laboratory tests according to a set CLFS initially established in 1984 and based on 1983 charge data. Fees are assigned based on the CPT or Healthcare Common Procedure Coding System (HCPCS) code established for each procedure (16, 17). Prior to the enactment of the Protecting Access to Medicare Act (PAMA) in 2014, the actual Medicare payment was the lowest of (i) the actual charge, (ii) the fee schedule amount set by the Medicare contractor, or (iii) the national fee cap, termed the national limitation amount (NLA). For tests established before 1 January 2001, and before PAMA, the NLA was set at 74% of the median of local fees, a percentage that had been rapidly reduced from 115% in 1986. Local fees were set at 60% of prevailing charges (except for sole community hospitals, which were set at 62%). Thus, Medicare payments were set to be substantially lower than actual charges. In addition, there was previously significant geographic variation in the actual payment amount based on the Medicare contractor. Medicare clinical laboratory payments are also not subject to copayments, a situation endorsed by the laboratory community, as billing costs often exceed the copay amount.

Adjustments were also made to the NLA on a regular basis. After 2001, as a result of the Balanced Budget Act of 1997, the NLA was set at 100% of the median to allow for improved reimbursement for new CPT codes, ostensibly representing emerging technology. For other test codes, the CMS adjusted the fee schedule annually to reflect changes in the consumer price index (CPI). However, in response to a number of federal budgetary "fixes" mandated by various statutes enacted since 1990, the actual adjustments were zero or a negative percentage for 14 of the 23 ensuing years, primarily due to fee schedule CPI "freezes." In addition, the Medicare program had the authority to mandate modifications in fees (increases or decreases) that were viewed as inappropriate or unreasonable. One strategy was termed "inherent reasonableness." Under this strategy, the CMS could employ "reasonable-charge methodology" to arbitrarily reduce or increase an NLA deemed "grossly excessive or grossly deficient" against market values. In point of fact, reasonable-charge methodology resulted primarily in reduced payments. On occasion payments were adjusted upward, as in 1999 when it was determined that cervical cytology (Pap smear) payment amounts were unreasonably low. In addition, reasonable charge methodology was used for laboratory services at critical access hospitals to help ensure beneficiary access. Another strategy, termed the "least costly alternative" approach, made a determination that a new more costly procedure had the same clinical utility as a less costly alternative, and payment was adjusted to that of the older methodology, thus impeding the implementation of new technologies. In contrast, laboratories have successfully withstood several attempts to lower payment amounts due to a competitive bidding model. Despite representing less than 2% of total Medicare expenditures, the laboratory has been a repeated target of a disproportionate share of attempted Medicare savings.

Fee-setting on the CLFS underwent a major modification upon implementation of PAMA in 2018 (18). This legislation mandated that payments would be based on the actual market price of tests. Determination of market price was based on submission of data from applicable laboratories. The definition of an applicable laboratory has been the subject of much debate as the current definition excludes most hospital laboratories and relies on data from larger reference laboratories. Data submission was mandated for specified time periods and was to be repeated every 3 years with CLFS payments based on the weighted median of private payor rates. Any reductions in payments were to be phased in over a period of several years with a maximum established for each year. The COVID-19 pandemic has significantly altered the time frames for data collections as well as the actual payment adjustment. However, the system is getting back on track and will remain the mechanism for CLFS price setting for the near future. There have been repeated legal challenges to PAMA and new legislation has been proposed that will address some of the issues encountered (for example, the Saving Access to Laboratory Services Act, SALSA). However, at the time of this writing, such legislative changes have not occurred. Regardless of the methodology used, CLFS payment amounts are published annually on the CMS website in the fall and are effective the following 1 January.

Fee Setting for New Codes on the CLFS

For new CPT test codes, Medicare fees are assigned based on one of two methods: cross-walking or gap filling. Cross-walking is used when new tests employ a method that is

本书版权归John Wiley & Sons Inc.所有

deemed comparable to an existing method or combination of methods, and the fee is simply set according to that of the existing code(s) to which the new code is mapped. Gap filling is used when a new code describes a test using a novel technology for which no comparable code exists. The fee is then set after collection of data by local contractors, who then apply the formulas previously described. Since 2001, the process of assigning fees to new codes has involved annual open meetings in which laboratorians and professional laboratory groups may present public recommendations on the best method to use. With the implementation of PAMA, additional input is provided by a CMS-appointed Advisory Panel on Clinical Laboratory Diagnostic Tests. After public comments and Advisory Panel recommendations are reviewed, proposed fees and the rationale for setting each are published by the CMS for comment prior to the final publication of the CLFS for the next year. For Advanced Diagnostic Laboratory Tests (ALDTs), which often have Proprietary Laboratory Analyses (PLA) codes and are reviewed quarterly, the fee-setting process is slightly different. Fees are paid initially based on charges, but subsequently subjected to a weighted median method based on annual data submission.

It is something of a paradox in the Medicare fee schedule process that a laboratory may have to accept a fee lower than its costs but has no recourse for recouping costs other than to develop strategies aimed at other payors (19). This paradox led the Institute of Medicine (20) to issue 6 of 12 recommendations in its report on Medicare laboratory payment policy pertaining to the fee schedule. These recommendations were (i) that "Medicare payments for outpatient clinical laboratory services should be based on a single, rational, national fee schedule"; (ii) that "on an interim basis, relative payments for Medicare outpatient clinical laboratory services should be based on the current NLA"; (iii) that "a data driven consensus process" be used to refine the Medicare fee schedule; (iv) that fees be "adjusted for geographic location" and evaluated for other circumstances "likely to affect beneficiary access"; (v) that there be processes to "periodically update" the fee schedule; and (vi) that there be an "open, timely, and accessible process" to incorporate new tests into the fee schedule that does not "impede clinical decision making that is essential to providing appropriate care." These goals have been largely met, including by the processes put in place by PAMA, but the push is clearly to lower costs of healthcare, including in the laboratory setting (21). However, recent data demonstrate that the opposite effect may occur (22), particularly as regards newer genomic medicine tests (23).

The Medicare Physician Fee Schedule

Clinical laboratory tests that have both a technical component and a physician interpretation component have the professional component priced on the Medicare Physician Fee Schedule (PFS). These include primarily anatomic pathology and cytology services and are subject to a copay by beneficiaries. Payments on the PFS are updated according to a complex formula for both technical and professional components and include consideration of relative value units for physician, practice, and malpractice expense adjusted by a conversion factor based on the geographic practice cost indices. A statutory change was introduced in 1998 using the sustainable growth rate to ensure that Medicare expenditures did not exceed targets. This approach has proved to be very problematic, with double-digit reductions projected some years. To prevent loss of patient access to services, Congress has stepped in many years to prevent such dramatic decreases. However, the future of payment adjustments for the PFS is uncertain, and a permanent solution is needed. PFS payments are updated annually each fall and are effective 1 January.

Other Fee Schedules

The importance of the Medicare fee schedules, both the CLFS and the PFS, is quite simply, the impact on the fee schedules developed by other third-party payors. Medicare fees are generally a starting point for negotiations between laboratories and other payors, which may lead to the deep discounts and special pricing situations already discussed. Alternatively, forced acceptance of lower fees may result in setting higher charges for noncontracted entities (e.g., patients) to attempt to achieve a break-even status. The adage "as goes Medicare, so go other payors" is of particular relevance in the realm of payment for services.

Capitated Payments

Capitated contracts for laboratory services are somewhat uncommon in outpatient arenas, but they may play a major role in the provision of laboratory services in extremely cost-constrained markets. In federal programs, there are a number of examples of capitation for laboratory services in managed-care Medicaid programs, and capitation will likely emerge in the managed-care Medicare Part C programs. The Medicare ambulatory payment classification and payment system for clinical services also currently includes most laboratory testing services. Accountable care organizations being developed under healthcare reform are almost certainly going to use capitation as a means to control costs. In other managed-care environments, such as health maintenance organizations (HMOs), laboratories may also be asked to develop a capitated payment scheme. In laboratories, a common payment mechanism is a per-member-per-month basis for provision of the most common laboratory services, with a separate fee schedule often appended for high-cost, esoteric services "carved out" of the capitated contract.

Inpatient service reimbursement may also be considered a type of capitated payment. Medicare and most other

本书版权归John Wiley & Sons Inc.所有

payors generally reimburse for inpatient stays as a specified amount based on either a diagnosis-related group or a per diem amount. To document both labor and financial input and to justify resources needed to provide services, laboratories should keep complete documentation of all activities through accurate and complete coding. This information can also be used in future negotiations with specific payors.

Certain healthcare environments represent a hybrid between retrospective and prospective payment systems. End-stage renal disease dialysis facilities are reimbursed a composite amount, which includes some laboratory services, while other additional services may be billed separately. Testing done for patients in skilled-nursing facilities is usually done by contract with an independent laboratory, while the actual stay is reimbursed as a Medicare Part A capitated amount, and other third-party payors generally follow the Medicare model.

Keys to Success in Reimbursement

Regardless of the type of payment situation, there are a few key actions that can help guarantee that a laboratory will be able to attain a reasonable profit or, at the least, avoid any significant losses in fulfilling its mission to provide high-quality, clinically relevant information at a reasonable cost. Integral to this process is a firm understanding of costs for procedures as well as correct coding for procedures performed and complete knowledge of all billing rules promulgated by a given payor (Table 33.1).

Retrospective Payment

The primary key to success in a retrospective (fee-for-service) payment situation is to obtain payment for all services that a physician orders and that you perform and for which you report the result. Therefore, you should code correctly and completely for all that you do and bill for all that you code for. In any situation in which more than one code applies, or if a procedure is added on by request or as a reflex, the associated codes should be added to the bill. You should obtain the diagnosis, preferably as an International Classification of Diseases, Clinical Modification code (ICD-CM), but translation of a narrative diagnosis into an ICD-CM code is generally acceptable. The diagnosis will help to satisfy any documentation requirements that a payor may have to determine whether a service is covered. One should obtain a waiver of financial liability (e.g., an advance beneficiary notice for Medicare Part B) from the patient in any situation in which there is a question as to whether the payor will cover the services. Finally, make every effort to price the charge at a level at least equal to the cost per reportable test and preferably at a level that maintains a reasonable profit while remaining competitive in the marketplace.

Table 33.1 Key concepts related to successful reimbursement

Costs	Know your actual/total costs for any given orderable and billable procedure
Charges and fee schedules	Set charges and accept fee schedules or other payments to guarantee a reasonable profit margin
Market competition	Set charges to be market competitive and provide services that are equivalent to or better than those of your competitors (value-added services)
Compliance	Avoid any appearance of inducement or kickbacks

Prospective Payment

The primary key to success with prospective (capitated) payment is also correct and complete coding. To determine if a proposed payment amount is acceptable, you must know (or project) the utilization rates for services, including rates of use of add-on and reflex tests. You should understand the patient mix according to diagnoses and/or medical subspecialty to help project utilization of specific, especially esoteric or niche tests. You must certainly know your costs by CPT code and must project total expenditures based on the terms of the contract. If certain esoteric tests are extremely high cost, you may wish to carve out those services and amend the agreement with a separate fee schedule for specific services. As is the case for retrospective payment situations, if the proposed terms of a prospective payment agreement are not financially favorable, you can decline to execute a contract to provide services.

Value-Based Payment

The primary contribution of the laboratory to value-based payment approaches is to ensure that any metrics involving laboratory testing be substantiated by documentation of tests performed with results that are aligned with performance metrics. While laboratory payment may not be impacted directly, the impact on an institution could be substantial if a payment reduction results from poor performance on the clinical condition being monitored. Such is the case with Medicare payments under the Hospital-Acquired Condition Reduction Program, which often relies on laboratory data to define conditions, particularly infections assessed through the National Healthcare Safety Network (24).

SUMMARY

In considering payment for laboratory services, there are four key concepts to remember (Table 33.1). First, know your actual costs for any given orderable and billable procedure, and make sure the terms of the payment agreement allow the recovery of costs. Second, set charges and accept fee schedules or other payments to guarantee that a reasonable profit margin has been

本书版权归John Wiley & Sons Inc.所有

attained. To continue to develop any laboratory business unit, it is essential to generate revenue that can be used to enhance the services offered. Beyond simply paying the bills, profits are essential for additional research and development, for facility improvements, for professional development of employees, and in the case of a for-profit entity, for generating returns on investments. Third, set charges to be market competitive and provide services that are equivalent to or better than those of your competitors. "Better than" is synonymous with "value-added" and includes developing a strong and knowledgeable customer support team. Finally, avoid any appearance of kickbacks. Under the OIG compliance program guidance for clinical laboratories, it is essential to avoid any appearance of inducement of ordering providers to submit testing from patients under federal payment programs. All of these concepts make for good clinical laboratory practice and also ensure that one is equipped to make good business decisions.

The establishment of reimbursement for laboratory services is a complex process with a variety of possible payor–provider relationships. Many relationships fail to make financial sense, and laboratories must carefully assess each potential client for impact. Increasing use of prospective payment systems will only make it more difficult for a laboratory to determine if an arrangement makes financial sense. A recent IOM report on providing "Best Care at Lower Cost" (21) provides a very accurate analogy for laboratory pricing: "If shopping were like healthcare, product prices would not be posted, and the price charged would vary widely within the same store, depending on the source of payment." Clearly, improvements to the process are both desirable and ongoing.

KEY POINTS

- The responsibility for cost analysis of individual laboratory procedures rests primarily with the laboratorian.
- To have a clear understanding of the total costs of a procedure, the best parameter to use is the cost per reportable test.
- The determination of charges has both financial and compliance implications; one generally does not charge below cost (which may be construed as an inducement for ordering providers) or substantially in excess of usual charges.
- The Medicare fee schedule is quite complex and is adjusted regularly, and payments can be substantially lower than actual charges. A laboratory may have to accept a fee lower than its costs and assess other mechanisms to remain financially sound.
- The importance of the Medicare fee schedule is its impact on the fee schedules developed by other third-party payors.
- The laboratory must maintain a thorough understanding of coding for procedures performed, as well as complete knowledge of all billing rules for each payor.
- Payment for laboratory services is based on four key concepts: (i) know your real test costs, (ii) set charges and accept fee schedules that guarantee a reasonable profit margin, (iii) set charges to be market competitive and provide services that are better than those of your competitors, and (iv) avoid any appearance of kickbacks.

GLOSSARY AND APPENDIXES

Reader please note that the Glossary and Appendixes for the three chapters in this section are combined and presented at the end of chapter 31.

REFERENCES

1. **NCCLS**. 1998. Basic Cost Accounting for Clinical Services: Approved Guideline. NCCLS GP-11-A. NCCLS, Wayne, PA.

2. **Wagar EA**. 2019. Financial management of the laboratory, p 173–188. *In* Wagar EA, Horowitz MB, Karcher DS, Siegal GP (ed), *Laboratory Administration for Pathologists*, 2nd ed. CAP, Northfield, IL.

3. **Wilkinson I**. 1999. *Money! Money! Money! A Hitchhiker's Guide to Laboratory Finance*. AACC Press, Washington, DC.

4. **The Lewin Group**. 2008. Laboratory medicine. A national status report. https://www.lewin.com/content/dam/Lewin/Resources/Site_Sections/Publications/3993.pdf. Accessed 1 March 2023.

5. **Kovar M**, **Shannon E**. 2011. Laboratory pricing: charge master risks and rewards. *N Perspect* **30**:15–17.

6. **Federal Register**. 2007. Medicare and state health care programs: fraud and abuse; clarification of terms and application of pro-gram exclusion authority for submitting claims containing excessive charges. *Fed Regist* **72**:33430–33432.

7. **OIG**. 1999. Advisory Opinion 99-13. https://oig.hhs.gov/documents/advisory-opinions/407/AO-99-13.html. Accessed 1 March 2023.

8. **Arvisais-Anhalt S**, **McDonald S**, **Park JY**, **Kapinos K**, **Lehmann CU**, **Basit M**. 2021. Survey of hospital chargemaster transparency. *Appl Clin Inform* **12**:391–398.

9. **Kona M**, **Corlette S**. 2022. Hospital and insurer price transparency rules now in effect but compliance is still far away. Health Affairs Forefront. https://www.healthaffairs.org/content/forefront/hospital-and-insurer-price-transparency-rules-now-effect-but-compliance-still-far-away. Accessed 15 October 2023..

10. **Kullgren JT**, **Fendrick AM**. 2021. The price will be right—how to help patients and providers benefit from the new transparency rule. *JAMA Health Forum* **2**:e210102.

本书版权归John Wiley & Sons Inc.所有

11. **Robinson JC**, **Whaley C**, **Brown TT**. 2016. Association of reference pricing for diagnostic laboratory testing with changes in patient choices, prices, and total spending for diagnostic tests. *JAMA Intern Med* **176**:1353–1359.

12. **Federal Register.** 2022. Requirements related to surprise billing. *Fed Regist* **87**(165):52618–52655.

13. **USDOL**. 2022. Fact sheet. Requirements related to surprise billing: final rules. https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/requirements-related-to-surprise-billing-final-rules-2022.pdf. Accessed 1 March 2023.

14. **Sinaiko AD**, **Kakani P**, **Rosenthal MB**. 2019. Marketwide price transparency suggests significant opportunities for value-based purchasing. *Health Aff (Millwood)* **38**:1514–1522.

15. **Fetter K.** 2022. Setting labs up for success amidst the No Surprises Act roll out. MLO On-line. https://www.mlo-online.com/management/reimbursement/article/21260876/setting-labs-up-for-success-amidst-the-no-surprises-act-roll-out. Accessed 1 March 2023

16. **Longberry J**. 2009. The clinical laboratory fee schedule yesterday, today, tomorrow. *Clin Lab Sci* **22**:99–104.

17. **Panning R**. 2014. Current status of clinical laboratory reimbursement. *Clin Lab Sci* **27**:119–126.

18. **Borden A**, **Showalter D**, **Storchan G**, **Hughes K**. 2015. The diagnosis for diagnostics: changes to Medicare payment and coverage of clinical laboratory tests. *Am J Manag Care* **21**(SP12):407–408.

19. **OIG**. 2013. Comparing lab test payment rates: Medicare could achieve substantial savings. OEI-07-11-00010. https://oig.hhs.gov/oei/reports/oei-07-11-00010.pdf. Accessed March 2023.

20. **IOM**. 2000. *Medicare Laboratory Payment Policy Now and in the Future*. National Academy Press, Washington, DC.

21. **IOM**. 2012. *Best Care at Lowest Cost. The Path to Continuously Learning Health Care in America*. National Academy Press, Washington, DC.

22. **GAO**. 2018. Medicare laboratory tests. Implementation of new rates may lead to billions in excess payments. https://www.gao.gov/products/gao-19-67. Accessed 15 October 2023.

23. **Klein RD**. 2020. Current policy changes in genomic medicine. *Clin Chem* **66**:61–67.

24. **CMS**. Hospital-acquired condition reduction program (HACRP). https://www.cms.gov/medicare/quality/value-based-programs/hospital-acquired-conditions. Accessed 15 October 2023.

本书版权归John Wiley & Sons Inc.所有

VII

Reimbursement, Compliance, and Profitability

(SECTION EDITORS: **Vickie S. Baselski and Alice S. Weissfeld**)

34 Rules and Regulations in Reimbursement
Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

35 Reimbursement Compliance
Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

36 Determination of Profitability
Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

本书版权归John Wiley & Sons Inc.所有

本书版权归John Wiley & Sons Inc.所有

34

Introduction
General Criteria
Basic Rules
Procedure Code Edits
Basic Edits • National Correct Coding Initiative • Mutually Exclusive Codes • Comprehensive/Component Edits • Medically Unlikely Edits • Add-On Code Edits • Appropriate Use Edits
Conditions of Coverage
Medical Necessity • National Coverage Determination • Local Coverage Determination • Medicare Coverage Database • Screening Tests • Experimental Testing • Administrative Policies
Special Coverage Conditions
End-Stage Renal Disease • Skilled-Nursing Facility • Ambulatory Payment Classifications • Inpatient Payment Classifications • Three-Day Window • Date of Service Rule • Other Private-Payor Rules
Remittance Advice Review
Beneficiary Documents • Provider Documents • Auditing Remittance Advice
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES
APPENDIXES

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch34.

Rules and Regulations in Reimbursement

Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

OBJECTIVES

To discuss the rules set forth by third-party payors that determine claim payment

To describe the term "medical necessity" and its relationship to reimbursement

To discuss the importance of claim compliance to reimbursement

To describe certain special coverage conditions for which unique billing rules may apply

To discuss national coverage determinations and the relationship between these determinations and local coverage determinations

To describe the most common reasons for reimbursement denial and what can be done to correct the problems

Call them rules or call them limits, good ones, I believe, have this in common: They serve reasonable purposes; they are practical and within a child's capability; they are consistent; and they are an expression of loving concern.

"Mister" Fred Rogers (1928–2003)

Beyond the basic logistical issues surrounding the battle for laboratory reimbursement are a number of issues that pertain to the rules of engagement. The logistical aspects include the documentation of what is done through Current Procedural Terminology (CPT) and Health Care Common Procedure Coding System (HCPCS) coding, why it is done through International Classification of Diseases, Clinical Modification (ICD-CM) or alternative diagnosis coding, where it is done through the use of revenue and place-of-service codes, and what the actual billing processes and amount of payment are (see section VI). The rules of engagement pertain to the establishment of criteria for the actual execution of payment, also known as conditions of coverage. Providers must meet all conditions imposed by regulations as well as terms of business set upon them by payors. In addition, to evaluate services for appropriateness for coverage and subsequent payment, payors generally employ standard sets of prepay edits, which specify clinical conditions for payment or nonpayment. Further, payors often conduct postpay audits to evaluate the accuracy of claim payments based on the defined coverage conditions. It is abundantly clear that the goal of a payor is to not pay when payment is unwarranted. At the same time, many payors also seek to severely restrict payment, and it is rather telling that the amount actually spent on healthcare services is termed the "medical loss ratio" rather than a "healthcare expenditure

本书版权归John Wiley & Sons Inc.所有

ratio." While it might be a stretch to compare these payment rules to the limits imposed upon a child by a parent, they do share some common features. They are basically simple and clearly defined; they are relatively easily applied through an electronic claim review process; and they represent a form of "tough love" in that they attempt to place some controls on the excessive spending associated with healthcare out of concern for the effective management of healthcare resources. Unfortunately, one can easily find examples of errors in the reimbursement system, thus strengthening the need for well-defined limits. While the focus of this chapter is the conditions payors place upon providers, one should recognize that payors are also subject to rules governing good business practice.

Reader please note that the Glossary and Appendixes for the three chapters in this section are combined and provided at the end of this chapter.

General Criteria

Criteria for conditions of coverage for laboratory services historically have as their bases a number of elements. First is the evidence-based-medicine element, which specifies that laboratory services should be covered if shown in the medical literature to be necessary, safe, and effective in the management of a particular condition. Second is the medical-ethics element, which suggests that patients should not be denied a procedure proven to be necessary, safe, and effective. Third is the medical-judgment element, which places the burden of decision making on the ordering provider, whose training and experience in patient management should justify performance of a procedure. These criteria have been traditionally adequate to determine coverage. However, as healthcare costs have risen, and rationing of available resources has become a necessity, more uniform and systematically applied criteria to verify that a service should be covered have emerged in the form of payor rules, which in federal payment programs are based on the interpretation of regulations arising from statutes. These rules are applied through stringent claim review processes in which both procedures and diagnoses are considered in making a payment determination (1, 2).

The primary statute upon which federal programs are based is the Social Security Act of 1967. This provided for healthcare benefits for "the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part" in the elderly and, subsequently, in disabled individuals. Many regulations have evolved from this phraseology, which limits services to those that have been interpreted by the Centers for Medicare and Medicaid Services (CMS) and its contractors as meeting the intent of the law. Furthermore, many other third-party payors have adopted similar types of payment rules. These rules can be divided into three general categories: those that are basic and review a claim for standard identifying information, those that evaluate the appropriateness of the procedures that are ordered in a given time frame, and those that assess the "medical necessity" of performing a test in view of the established coverage criteria.

Basic Rules

The claims for laboratory services must meet certain basic requirements for processing. The coding requirements for claim transactions have been standardized under the Health Insurance Portability and Accountability Act (HIPAA), and the CMS requires submission of all standard code and transaction sets. CMS claims are filed using one of two basic formats for laboratory services that are used in their entirety or as models for claims submitted to other payors. Form CMS-1450 (formally UB-92) is used for institutional (e.g., hospitals, nursing homes) claims for Medicare Part A services. It is designed and maintained by the National Uniform Billing Committee and used by many institutional providers. Form CMS-1500 is used by noninstitutional providers (e.g., independent laboratories) to bill Medicare Part B services and some Medicaid services, and it has become a universal claim form for many other third-party payors. While these are manual forms, the required data elements are the same as those in electronic forms. As a result of the Administrative Simplification and Compliance Act of 2001, providers are required to submit electronic claims after October 2003, with only a few exceptions. Under HIPAA, the Department of Health and Human Services has adopted ASC X12 (Accredited Standards Committee) Version 5010 as the HIPAA standard for electronic transactions after January 2009, with mandatory implementation as of January 2012. Importantly, form 5010 is able to accommodate the ICD-10-CM (International Classification of Diseases, Clinical Modification, 10th edition) codes required since 2014.

The major required elements for claim submission and subsequent reimbursement for covered services are defined in general by CMS (3) and are as follows (Table 34.1). The patient must be identified using a unique identifier, and all demographic information necessary for subsequent communications, particularly bills for services if indicated, must also be provided. The date of service, which is defined as the date of collection of clinical specimens, must be provided. The ordering provider must be identified using a national provider identifier, or NPI (previously called the unique provider identifier number, or UPIN), and adequate demographic information must be provided for subsequent communications, including acquisition of additional documentation, test results, and bills for services if indicated. The authentication of the laboratory service provider requires a Clinical Laboratory Improvement Amendments (CLIA) number and designation (high complexity, moderate complexity, certificate of

本书版权归John Wiley & Sons Inc.所有

Table 34.1 Major required elements for claims submission and subsequent reimbursement

Unique patient identifier
Date of service
Bills for services
Ordering provider number (national provider identifier)
Provider CLIA[a] number and designation (high complexity, moderate complexity, certificate of waiver, provider-performed microscopy)
Place of service (either revenue code for inpatient testing or place-of-service code for outpatient testing)
Actual services provided (CPT or HCPCS codes, including units of service and modifiers where appropriate, and actual charges for each service)
Reason for performing the test (ICD-9-CM or ICD-10-CM diagnosis code for outpatients and DRG or narrative diagnosis for inpatients)

[a] Clinical Laboratory Improvement Amendments.

waiver, provider-performed microscopy) appropriate to the service being billed. The place of service must be designated, either as a revenue code in the case of an inpatient or using a place-of-service code for outpatient testing. The actual services provided on the specified date must be indicated using the appropriate CPT or HCPCS codes, including units of service and modifiers where appropriate as well as the actual charges for each service. Reimbursement is not generally made at the charge level, but Medicare and other third-party payors may use this information for determination of fee schedule payment amounts if not already established through the Protecting Access to Medicare Act (PAMA) market-based process. Finally, the reason for performing the test must be indicated using an appropriate ICD-CM diagnosis code for outpatients and a diagnosis-related group (DRG) or ambulatory payment classification (APC) for hospital inpatients and outpatients, respectively. Failure to complete all required data fields is likely to result in a denial of payment from any third-party payor (4).

Table 34.2 Procedure code edits

Basic edits	Determination of whether a service may represent a duplicate service (review of actual procedures identified by HCPCS or CPT codes) Frequency limits (how often a particular laboratory procedure may be reimbursed); it may be necessary to obtain an ABN for frequency-limited test procedures
NCCI	Review to determine if two or more different codes are appropriately ordered on the same date of service. NCCI provides an extensive system for this type of claim review process, administered through Correct Coding Solutions, LLC (Medicare contractor) Documents published on quarterly basis; available on the CMS website or as a printed version from the NTIS
Comprehensive/ component edits	These edits identify cases in which a specific code has been identified as representing a component of a more comprehensive code documented on the same date of service (AMA[a]-approved panel—one would not also code and bill for individual analytes included in the panel)
Mutually exclusive codes	Codes for services that are not reasonably performed during the same patient encounter; these codes are considered to provide duplicate information Multiple tests to identify the same analyte, marker, or infectious agent should not be reported together
Medically unlikely edits	Frequency edits that delineate the number of units of a specified CPT code that can be billed on a single day of service
Add-on code edits	Codes that can only be applied as a follow-up procedure to another code on a specific day of service
Appropriate use edits	Used in radiology to determine best procedures to use based on a decision support system; not currently in use in laboratory medicine but have potential to be implemented

[a] American Medical Association.

Procedure Code Edits

Basic Edits

The next category of prepay edits used for claim review evaluates the actual procedures performed as identified by HCPCS or CPT codes (Table 34.2). The most basic edit is a determination of whether a service may be a duplicate service (i.e., same procedure on the same date of service). If a laboratory procedure is performed more than once on a given date of service for a valid medical purpose, an appropriate modifier (-59 or -91) must be appended to the procedure code. Similarly, frequency limits are used to determine how often a particular laboratory procedure may be reimbursed. These types of edits may be problematic for clinical laboratories if a patient has presented to more than one ordering provider or laboratory provider during the time frame for reimbursement. For this reason, it is reasonable to obtain an advance beneficiary notice (ABN) for frequency-limited test procedures.

National Correct Coding Initiative

Procedure codes are also reviewed to determine if two or more different codes are appropriately ordered on the same date of service. The Medicare National Correct Coding Initiative (NCCI) provides the most extensive system for this type of claim review process. This program was initiated by the CMS in 1996 and is maintained through a contract with a designated Medicare contractor.

本书版权归John Wiley & Sons Inc.所有

The program is designed to promote correct coding of healthcare services, including laboratory services, and to control improper payment for incorrect coding. Edits have been developed based on national and local coverage policies, coding guidelines and practice guidelines published by professional societies, and review of provider current coding and billing practice. The Medicaid program is also subject to NCCI edits, and while substantially in line with Medicare edits, there may be some differences and laboratories should be familiar with both.

The NCCI documents are updated quarterly, and electronic versions are publicly available on the CMS website. The complete document includes a table of contents and 13 narrative chapters, with chapter X specific to pathology and laboratory services. However, on occasion, there is crossover between chapters in edit pairs, and laboratorians should be aware of all edits pertaining to the laboratory. NCCI is provided to contractors as a set of automated edits that examine all CPT and HCPCS codes submitted on the same date of service. As expected, NCCI also serves as a model for claim review by other third-party payors. The edits fall into several types but are now combined into a single listing of edit pairs in two columns, termed procedure-to-procedure edits. For codes that appear in these columns, payment is made only for the code in column 1 and payment is denied for any associated codes in column 2. The edits also indicate the code pairs in the columns for which a modifier (generally -59) may be appropriate to indicate that the tests were in fact unique and appropriate under the circumstances. Because denials are due to incorrect coding, an ABN is not appropriate for use to render patients financially liable for payment.

The NCCI contractor bases the edits on a number of features of CPT codes. Particular attention is given to the narrative descriptors for the codes to determine if the code is appropriate for use more than once per date of service. In addition, narratives are evaluated to determine if two or more codes provide the same information, in which case codes are deemed mutually exclusive. Narratives are also evaluated to determine if elements of one code are embedded in another code, in which case the edit is considered a comprehensive/component edit.

Mutually Exclusive Codes

Mutually exclusive codes are those that are not reasonably performed during the same encounter. In essence, these are considered to provide duplicate information. There is a long-standing CMS interpretation of the Medicare statute that has influenced the development of mutually exclusive edits; that is, multiple tests to identify the same analyte, marker, or infectious agent should not be reported together. For example, it would not be appropriate to perform an enzyme immunoassay and a nucleic acid detection procedure to detect the same infectious agent from the same specimen on the same date of service, nor would it be appropriate to perform and bill a nonamplified and an amplified nucleic acid test for the same analyte from the same specimen on the same date of service. Again, if additional clinically useful information may be obtained by performing both procedures in a mutually exclusive code set, modifier -59 may be attached in specified circumstances. When mutually exclusive codes are billed together inappropriately, in general, the lower-paying code is the code that is reimbursed.

Comprehensive/Component Edits

Comprehensive/component edits identify cases in which a specific code has been identified as representing a component of a more comprehensive code documented on the same date of service. The most obvious example is the performance of an American Medical Association–approved panel. In this situation, one would not also code and bill for the individual analytes included in the panel unless a subsequent measurement of a specific analyte was necessary for patient care. In other cases, the descriptor for a procedure may include several related codes. All of the molecular infectious disease codes are considered inclusive of all individual procedural step codes previously found in the chemistry section of the CPT codebook as molecular diagnostic procedural steps. It should be noted that these procedural step codes (termed "stacking codes") were eliminated in 2013 and all noninfectious analytes were reassigned to a new, analyte-specific molecular pathology section similar in design to molecular microbiology codes first developed in 2001. Finally, if after a test is ordered and performed, an additional related procedure is necessary to confirm the result, this would be considered a part of the original ordered test unless a specific confirmatory code is available (e.g., in the case of several serologic tests for infectious agents, including human immunodeficiency virus and *Treponema pallidum*, and for hepatitis B surface antigen). When incompatible comprehensive edit code pairs are billed, the most comprehensive code, but not the component codes, is generally reimbursed. As for mutually exclusive codes, these edit pairs may also allow use of modifier -59 in some cases if the component test is determined to be appropriate for the circumstances. It can be extremely challenging for laboratorians to assess how the NCCI process applies to their standard operating procedures and subsequent billing for procedures performed.

Medically Unlikely Edits

In 2007, the NCCI established an additional set of edits known as medically unlikely edits (MUEs). An MUE is a frequency edit and represents the maximum number of units of service allowable under most circumstances for a single CPT or HCPCS code billed by a provider on a single date of service for a single beneficiary. MUEs are developed

本书版权归John Wiley & Sons Inc.所有

based on a number of considerations including CPT/HCPCS code descriptors, CPT coding instructions, anatomic considerations, established CMS policies, nature of service/procedure, nature of analyte, nature of equipment, and clinical judgment. Not all HCPCS/CPT codes have an MUE, and not all MUEs are published. For example, if the MUE is set at greater than 3, it is not published due to concerns about risk for overutilization. In addition, the MUE should not be considered as a guide for utilization, and any repeat testing should be clinically indicated. Since some MUEs are not published, careful claim denial review is often indicated to recognize that a frequency edit is operational.

Add-On Code Edits

Effective in 2022, a new add-on code section was developed. As the name implies, an add-on code would only be billed when the primary code was performed initially. Again, this can be challenging for a laboratory if the two procedures are performed in different laboratories.

Appropriate Use Edits

One new category of edits used for radiology procedures under PAMA and required since 2020 for advanced diagnostic imaging that may have relevance to laboratory tests in the future is "appropriate use criteria" (5). These criteria extend beyond simple coding parameters and attempt to assess clinical utility of procedures by requiring that orders be evaluated through an interactive electronic qualified decision support mechanism based on generally accepted standards of care. The purpose is to enable the provider to order the most appropriate test for a patient. It is entirely possible that similar edits could be applied to complex molecular pathology procedures.

Conditions of Coverage

The term "conditions of coverage" has two distinct meanings for reimbursement. First, the term may apply to the conditions that a healthcare provider must meet to be able to bill a payor and be reimbursed by that payor for a service. Also known as "conditions of participation," this may entail having the correct CLIA certificate and state facility and professional licenses, meeting patient notification requirements under HIPAA as well as providing patients notice of their rights, accepting assignment of specified payment amounts for services, and meeting all other applicable regulatory requirements. The second meaning applies to the conditions that a patient must meet for a service to be paid for. In this situation, "conditions of coverage" refers to a determination by a payor of the clinical circumstances under which a particular procedure will be paid for. Note that for both meanings, the payor sets the conditions of coverage and subsequent payment.

Medical Necessity

"Medical necessity" refers to a specific mechanism for defining conditions of coverage for a patient. Under Medicare, this terminology derives from Section 1862(a)(1)(A) of the Social Security Act of 1965, which stipulates that Medicare payment will be made only for expenses incurred for items or services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Medicare has consistently interpreted this provision to exclude services that have not been determined to be safe and effective, are experimental, and are not performed in accordance with accepted standards of medical practice as demonstrated through peer-reviewed literature and published professional society guidelines or practice standards (4). In addition, Section 1862(a) (8) excludes coverage for expenses for routine physical checkups and for testing performed to screen for an illness or an illness precursor in the absence of signs, symptoms, complaints, or personal history of disease or injury except where explicitly allowed by statute (e.g., cervical cytology in women and prostate-specific antigen testing in men) or by regulation. Note that coverage of preventive care services including laboratory services was significantly expanded under the Patient Protection and Affordable Care Act (PPACA or ACA).

Medical-necessity edits have been developed that specify both the procedures performed and the reason for performing the procedures on a given date of service. These edits may be developed and applied nationally and are known as national coverage determinations (NCDs). Alternatively, where there is not an NCD or where an NCD is silent, local policies may be developed by individual contractors. These are known as local coverage determinations (LCDs). However, a local contractor may not develop an LCD in conflict with an NCD. Both types of policies explicitly delineate the ICD-CM diagnosis codes, which are recognized as providing evidence of medical necessity for coverage of a particular laboratory procedure identified by CPT code. As would be expected, private third-party payors have embraced this concept, and while not as extensive as the system used for Medicare reimbursement, medical necessity nevertheless forms the basis for denials of payment in the private sector as well.

National Coverage Determination

Section 4554(b) (1) of the Balanced Budget Act of 1997 mandated the use of a negotiated rulemaking process to develop national coverage and administrative policies for Part B clinical diagnostic laboratory services (Table 34.3). Beginning in 1998 and continuing through 1999, 18 professional groups representing laboratory, physician, and beneficiary interests and the Department of Health and Human Services Medicare program participated in this process, culminating in the publication of

本书版权归John Wiley & Sons Inc.所有

Table 34.3 National coverage determinations[a]

Definition	Balanced Budget Act of 1997 mandated the use of a negotiated rulemaking process to develop national coverage and administrative policies for Part B clinical diagnostic laboratory services
Participation	From 1998 to 2000, 18 professional groups representing laboratory, physician, and beneficiary interests and the Department of Human Services Medicare program participated in this committee
Publications	National coverage policies developed through consensus; 23 policies are believed to represent 60% of the Part B laboratory outlays and provide consistency in coverage for beneficiaries
NCD format	Narrative description of the covered services and associated CPT codes Specific ICD-9-CM codes that may be covered, those that are generally not covered, and those that are never covered due to statutory interpretation (e.g., screening tests for diseases or disease precursors)
Content of narrative section	Defines indications, coding guidelines, and limitations
Updates	NCDs have been updated with technical corrections on a regular basis and communicated to payors and providers through program memoranda and transmittals issued by the CMS

[a]Note: The format for local coverage determinations is structurally similar.

23 national coverage policies developed through consensus. A notice of proposed rulemaking was published in March 2000, and a final rule was published in November 2001, with an implementation date 1 year hence. These 23 policies were believed to represent 60% of the Part B laboratory outlays and provided consistency in coverage for beneficiaries. Further, a system has been developed to allow for both the update of existing policies and for the continuation of the development of new NCDs through a formal, defined process (3).

The format for an NCD is also defined. A narrative description of the covered services is given, and the associated CPT codes are identified, as well as the ICD-CM codes that may be covered, those that are not generally covered, and those that are never covered due to statutory interpretation (e.g., screening tests for diseases or disease precursors). In addition, each NCD has a narrative section that defines indications, coding guidelines, and limitations upon which the coding portions are based. These NCDs are updated with technical corrections based on annual coding changes or new CMS interpretations and communicated to providers on a regular basis through transmittals issued by the CMS. During the claim review process, the procedure codes (CPT or HCPCS) that have been submitted are compared to diagnosis codes (ICD-CM) to determine if payment is appropriate. The NCD for urine cultures provides a good example of an NCD developed through the negotiated rulemaking process that has subsequently undergone a number of changes (6).

Local Coverage Determination

Where a national policy does not exist, or for any aspect of a national policy for which coverage conditions are not specified (e.g., frequency limits), a regional contractor may issue an LCD. The contents of LCDs are very similar to those of NCDs, and each contractor must develop software for claim review, again comparing procedure codes (CPT or HCPCS) to diagnosis codes (ICD-CM) to make a payment decision. A medical contractor advisory committee generally develops LCDs through a systematic process. LCDs are published in local contractor bulletins for a review-and-comment period (generally 90 days), after which a final policy is developed and implemented. The inequities in coverage promulgated by LCDs led to a Government Accountability Office recommendation that future LCD development be eliminated (7), and existing policies be evaluated to determine if they should be incorporated into national policies or rescinded. However, at this time LCDs are still being routinely developed and used by local contractors. Some, particularly those for emerging technology like molecular pathology tests, may be very restrictive and controversial.

Medicare Coverage Database

The Medicare Coverage Database contains all NCDs and LCDs, local articles, and proposed NCDs. The database also includes several other types of national coverage policy–related documents including national coverage analyses, coding analyses for laboratories, Medicare Evidence Development and Coverage Advisory Committee proceedings, and Medicare coverage guidance documents. It should be noted that other third-party payors similarly use medical review or health technology assessment (HTA) groups to develop coverage policies (8). These payors generally maintain coverage policies on websites. Laboratories should remain aware of all relevant coverage documents from both federal and other payors, particularly if medical-necessity denial trends are noted.

Screening Tests

Historically, preventive tests that screened for disease, disease precursors, or increased risk for disease in asymptomatic patients were not considered to meet medical-necessity indications under Medicare. Only a very few screening tests were reimbursed as a result of congressional action. However, under the Medicare Improvements for Patients and Providers Act of 2008, CMS now has the authority and the flexibility to add to the Medicare-covered preventive services, including laboratory tests, if there is sufficient evidence published such that the United States

本书版权归John Wiley & Sons Inc.所有

Preventive Services Task Force (USPSTF) issues a recommendation. Current Medicare screening benefits are extensive and were expanded under the PPACA and currently include a number of laboratory procedures (see Table 34.4). The CMS uses the NCD proposal process to make such new screening coverage decisions which are often based on recommendations made by the USPSTF. As expected, other third-party payors similarly set coverage conditions for specific screening tests.

Experimental Testing

Medicare has historically interpreted the "reasonable and necessary" clause to mean that services that are experimental (i.e., for research or investigational use) are not reasonable or necessary and therefore are not reimbursed. Further, clearance or approval by the Food and Drug Administration (FDA) is taken as evidence that a procedure is not experimental. Currently, however, there is much controversy in this area, particularly in the realm of newly emerging molecular technologies. Procedures with a category B investigational device exemption may be reimbursed at a contractor's discretion, as may routine tests used in support of a new investigational device or procedure in a clinical-trial setting (9). However, it is still generally accepted that failure to have FDA clearance or approval if required is justification for denial. In the case of laboratory-developed tests (LDTs) using analyte-specific reagents (ASRs), the tests may be approved for reimbursement by a contractor if the assay has been properly verified in accordance with CLIA regulations in a high-complexity laboratory, the ASR is being used in accordance with the ASR rule, and all other conditions for medical necessity are met (10). In many cases, such tests have received a PLA CPT code or PAMA advanced diagnostic laboratory test (ADLT) designation and have gone through a fee-setting process (11). In the case of other third-party payors, there tends to be more leniency in coverage, as payor-specific independent health technology assessment groups make individual coverage decisions. In addition, a recent trend of using laboratory benefit management programs, similar in concept to pharmacy benefit management programs, to facilitate coverage decisions is emerging (12). Coverage of complex genetic testing is currently a subject undergoing intense scrutiny as these assays tend to have relatively higher reimbursement than more routine laboratory tests (13, 14). One successful strategy used for colorectal cancer genetic screening coverage has been to undergo parallel review by the FDA and CMS simultaneously to expedite coverage determinations (15). Infectious disease multiplex testing is another area that has undergone intense scrutiny, with some payors issuing rather restrictive coverage policies limiting the number of analytes reimbursed (16). For example, respiratory pathogen panels were originally restricted to a low number of analytes, but the number has subsequently increased to account for increased clinical relevance in immunocompromised patients (17).

Administrative Policies

A number of Medicare administrative policies were also developed during the negotiated rulemaking process that remain operational (3). These policies were related to the actual processing of claims and required contractors to accept and evaluate all diagnostic codes submitted before making a medical-necessity determination, allowed a narrative diagnosis to be translated into an ICD-CM code if a match could be found, and forbade the use of unpublished frequency edits as a basis for denial of payment. In addition,

Table 34.4 Medicare coverage for screening benefits[a]

Condition	Test(s)	Frequency
Cardiovascular disease risk	Cholesterol, lipid, and triglycerides	Every 5 years
Cervical cancer	PAP and HPV testing	Every 24 months or 12 months if high risk
Colorectal cancer	Fecal occult blood	Every 12 months
Diabetes if at risk, e.g., high blood pressure, dyslipidemia, obesity, elevated glucose, age >65, family history, gestational diabetes	Fasting blood glucose	Up to twice per year
Hepatitis B	HBV serology, 3 markers	At least once per lifetime or as needed if at risk
Hepatitis C	HCV serology	At least once/lifetime or as needed if at risk
Human immunodeficiency virus if pregnant, at risk, or on request	HIV antibody ± antigen screening test	Every 12 months or up to 3 times in pregnancy
Prostate cancer	Prostate-specific antigen (PSA)	Every 12 months
Sexually transmitted infections if pregnant or at risk	Chlamydia, gonorrhea, syphilis, and hepatitis B	

[a]See quick reference guide at https://www.cms.gov/medicare/prevention/prevntiongeninfo/medicare-preventive-services/mps-quickreferencechart-1.html.

本书版权归John Wiley & Sons Inc.所有

although the laboratory remains the entity that receives payment and therefore is the entity at risk for nonpayment when a claim is denied, the policy did clarify that the ordering providers have a responsibility to submit required medical-necessity documentation. Further, if documentation is not provided, CMS contractors should notify the ordering provider that additional documentation is required to complete the claim for payment. The policies also clarified that absent evidence or clear proof of medical necessity, laboratories should seek beneficiary signing of an ABN assuming financial liability in the case of denial. Such documents are also common in third-party payor situations.

Special Coverage Conditions

The rules discussed thus far apply primarily to laboratory services for outpatient populations. In a number of other specific clinical circumstances, unique billing rules may apply (Table 34.5). In the Medicare program, special rules apply, particularly in the setting of end-stage renal disease (ESRD) and its management in dialysis centers and in payment for laboratory services in Part A skilled-nursing facilities (SNFs). Patients admitted to hospitals with preadmission testing are also subject to a rule called the "DRG payment window" prior to admission and to a "date of service rule" after discharge. Finally, each individual payor may impose other arbitrary rules that may be discerned only through careful evaluation of denials.

End-Stage Renal Disease

ESRD payment rules are rather complex and represent a combination of a capitated system and a fee-for-service system (18). Most clinical laboratory tests are included in a composite rate payment through the Medicare contractor. To bill separately according to the clinical laboratory fee schedule for additional tests, 50% or more of the covered tests must be noncomposite rate tests for a given date of service. This might apply in the case of an unexpected complication, for example an infection, requiring tests not generally performed to assess general physiologic condition. In addition, several unique HCPCS modifiers are used to identify a separately billable test.

Table 34.5 Special coverage conditions

ESRD	Complex payment rules that represent a combination of a capitated system and a fee-for-service system
SNF	All reimbursement is bundled into a single composite prospective payment; there are a few exceptions, but laboratory services are included in the composite per diem
Three-day window	Used to prevent transfer of charges from the capitated DRG system to a fee-for-service Part B system. Specifies that laboratory services performed by a hospital are included in the DRG payment for a related admission within the preceding 3-day period
Date of service rule	Tests ordered after discharge on existing samples within a 14-day window are covered under the DRG payment and not billed separately. May place costs for esoteric procedures on the hospital
Other private-payor rules	Third-party payors model coverage rules on Medicare; however, each has its own guidelines for reimbursement

Skilled-Nursing Facility

The Balanced Budget Act of 1997 altered the manner in which the majority of services are provided to Medicare beneficiaries in a Part A-covered SNF stay. All reimbursement was bundled into a single composite prospective payment. While there are a few exceptions that represent separately payable services, laboratory services are generally included in the composite per diem. In a Part B stay in which Part A benefits have been exhausted, certain medical services, including laboratory tests, may be payable according to the previously described rules.

Ambulatory Payment Classifications

APCs are used for prospective payment for outpatient services and include bundling of laboratory services into the capitated payment in most cases. In order to better control laboratory spending as healthcare reform progresses and accountable care organizations become predominant brokers for services, it is likely that capitated outpatient services including laboratory services will become an overarching theme.

Inpatient Payment Classifications

Laboratory services for hospitalized inpatients are often established to comply with additional sets of rules. Although edits such as the NCCI edits may form a basis for correct code utilization, it is equally important to apply other diagnosis- and institution-specific checklists to ensure that testing is performed according to established protocols. Since payment is made prospectively (e.g., by DRG), it is very important to establish laboratory protocols that contribute to safe and clinically effective patient management while expending resources in a rational and cost-effective manner.

Three-Day Window

Patients admitted to the hospital and eligible for Part A services frequently require preadmission testing. To prevent the transfer of charges from the capitated DRG system to a fee-for-service Part B system, Medicare implemented the 3-day payment window, which specifies that laboratory services performed 3 days prior to admission by a hospital or by an entity wholly owned or operated by a

本书版权归John Wiley & Sons Inc.所有

hospital are included in the DRG payment for the subsequent hospitalization. In certain specified care settings, the window is reduced to one calendar day (19).

Date of Service Rule

After discharge, there are also Medicare rules restricting payment for tests ordered on samples collected during the hospital stay. Tests ordered on existing samples within a 14-day window are covered under the DRG payment and not billed separately. This policy may cause delays in test ordering and may also place a hospital in an unfavorable reimbursement situation for more esoteric tests referred out for testing. Under a provision of the PPACA, alternate payment mechanisms for certain complex laboratory tests, particular molecular pathology tests, may be applicable.

Other Private-Payor Rules

While many third-party payors often model their coverage rules on Medicare, each has its own guidelines for reimbursement. A large laboratory may interact with several hundred unique payor plans, and the ability to triage claims for compliance with all payment rules absolutely depends on regularly updated claims-processing software. Fortunately, these payors tend to be more liberal in reimbursement for services, yet as healthcare costs rise, rules restricting payment for services will almost certainly become an attractive means to control costs.

Remittance Advice Review

Beneficiary Documents

The importance of review by the laboratory of the bases for denial or adjustment of claims by all payors cannot be overemphasized (20). For beneficiaries, a specific explanatory statement termed an explanation of benefits (EOB) or explanation of medical benefits (EOMB) accompanies each denial by any payor. In the Medicare program, a beneficiary receives a Medicare summary notice (MSN, previously termed an Explanation of Medicare Benefits). These documents provide specific and standardized explanatory information that identifies the reason for the denial. This information can be used to attempt to obtain additional documentation from the ordering provider to resubmit the claim, initiate an appeal process, or bill an alternative responsible party (i.e., client or patient) if appropriate.

Provider Documents

Laboratories also receive remittance advice reports from Medicare contractors and other payors that provide an explanation of the disposition of a claim for specific patients in a given period. These reports list the deficient items that are responsible for preventing expected payment. Under HIPAA, two sets of standardized codes are now required to convey this information to providers. The "claim adjustment reason codes" communicate why a claim for service was "adjusted" (i.e., paid differently from expected) and are maintained by the American National Standards Institute. The "remittance advice remark codes" add greater specificity and additional explanatory narrative to the reason codes. The CMS is the national maintainer for the standard reason and remark codes (21–23).

Auditing Remittance Advice

Careful review of these remittance documents provides a mechanism to identify billing problems that are costly in terms of both uncompensated labor and lost revenue (24). Recent data indicate that the most common reasons for denial include lack of medical-necessity documentation, the fact that the service performed is noncovered (generally if used for screening purposes), inadequacy or lack of basic identifying documentation (particularly date of service, ordering provider identifier number, and patient identification number), and incorrect coding (both procedure and diagnosis). Studying these reports to identify trends can identify systematic problems often resulting from a simple failure to follow the payor rules and can lead to successful interventions to correct the problems and enhance appropriate reimbursement. A number of case studies have demonstrated significant improvement in reimbursement after implementation of processes to ensure adequate documentation and compliance with rules prior to claim submission.

SUMMARY

Knowledge of and understanding of the rules set forth by third-party payors that determine whether a claim submitted for laboratory services will be paid are key to success in the laboratory. Many of the rules emanate from Medicare statutes, with resulting regulations that are designed to ensure that only services that are deemed medically necessary for management of a disease condition are paid for. However, in a number of circumstances, payment has been deemed appropriate for certain specific preventive medicine test procedures. Design of a system that attempts to ensure compliance with all of the known rules and regulations from federal and other payors can significantly reduce costly and time-consuming claim resubmissions. Likewise, the system will ensure timely reimbursement for services that are considered to be covered and allow for alternative billing of the appropriate responsible party in the event of a denial. Indeed, such rules lay consistent and logical, if not always mutually agreed upon, grounds for reimbursement. In addition, since the majority of these rules are published and readily accessible from payors, a systematic approach

本书版权归John Wiley & Sons Inc.所有

not only ensures payment for services, but lays a firm foundation for regulatory compliance (chapter 35).

KEY POINTS

- Medicare payor rules are based on regulations arising from statutes and often form the basis for claims review by other payors.
- Rules for reimbursement are applied through stringent claim review processes.
- Failure to complete all required data fields in a claim for laboratory services will result in a denial from a third-party payor.
- It is important to understand the types of prepay edits that can result in claim denials.
- Both procedures and diagnoses are considered in making a medical necessity payment determination.
- The concept of medical necessity forms the basis for claim denials in both the public (Medicare) and private sectors.
- It is important to understand how NCDs, LCDs, and other conditions of coverage are set and how to contact the payors for claim denial clarifications.
- It is important to recognize that postpay audits may be conducted by payors to ensure compliance with billing rules.
- Postpay audits may result in the laboratory being required to return payments if billing compliance problems are noted.
- The importance of reviewing all claim denials to identify trends for process improvement cannot be overemphasized.

GLOSSARY

Add-on code edit Pre-payment NCCI claim edits that ensure a primary code is used in conjunction with the add-on code.

Advance beneficiary notice (ABN) A waiver of liability used by the provider to notify Medicare beneficiaries prior to receiving a service that it may not be a covered service and that they may have to assume financial responsibility; similar notices used by other payors.

Adjudication (of a claim) Process by which payors review claims to determine payment or denial of payment.

Ambulatory payment classification (APC) Classification system used by CMS for outpatient prospective bundled payment for certain categories and levels of outpatient services.

American National Standards Institute (ANSI) A private organization that oversees development of and accredits nationally used standards. In the Medicare program, the claim adjustment reason codes are maintained by ANSI.

Analyte-specific reagent (ASR) An FDA-regulated category of reagents meeting specific quality requirements for clinical laboratories to use in developing laboratory-developed tests (LDTs). If the ASR is used in accordance with regulations and reasons for medical necessity are met, LDTs may be reimbursed at the discretion of a payor.

Anti-kickback statutes Laws that prohibit the exchange (or offer to exchange) of anything of value in an effort to induce (or reward) the referral of business reimbursable by federal healthcare programs.

Appropriate use criteria A program under PAMA designed to improve utilization of advanced diagnostic imaging services through use of a qualified decision support method (QDSM); not yet applied to clinical laboratory tests.

Billable test A CPT or HCPCS codeable test performed and charged to a patient, physician, or third-party payor account that generates revenues. The billable test is the focal point in laboratory cost accounting for laboratories that generate revenue.

Bundled Payments of Care Initiatives (BPCI) A CMS payment model that aims to support healthcare providers who invest in practice innovation and care redesign to better coordinate care and reduce expenditures in specific episode-of-care situations.

Bundling Placing multiple codes together in an orderable panel.

Civil False Claims Act and the Civil Monetary Penalties Law Statutes that authorize the Secretary of Health and Human Services to impose civil monetary penalties (CMPs) for violations of Medicare rules and regulations, as well as additional assessments for statutory violations of Medicare law.

Claim The manual or electronic document or invoice, which allows transmission of the bill for services to a payor.

CMS-1450 (formerly UB-92) Claim form used for institutional (e.g., hospitals, nursing homes) claims for Medicare Part A services.

CMS-1500 The claim form authorized by the Centers for Medicare and Medicaid Services for filing Medicare Part B claims with contractors. Previously designated the HCFA-1500 (Health Care Financing Administration).

CMS-5010 Standard form used for electronic claims submission. The CMS requires electronic submission with few exceptions.

Code jamming Inserting a code that was not provided by the ordering provider but that will justify payment.

Code steering Providing lists of diagnostic codes that are known to justify payment.

Comparative effectiveness In laboratory medicine, the systematic comparison of two or more approaches to determine whether one approach provides better patient outcomes than the other(s).

Compliance Program Guidance for Clinical Laboratories Model Clinical Laboratory Compliance Plan (1998) designed to ensure that appropriate reimbursement is made through federal programs, provides guidance for "paying it right" through compliance with all regulatory and statutory rules.

本书版权归John Wiley & Sons Inc.所有

Composite tests A grouping of individually codeable tests performed on the same date of service in accordance with generally accepted practice standards; may be billed individually or at a combined rate (e.g., ESRD rates).

Conditions of coverage A determination by a payor of the circumstances under which a particular procedure will be paid for.

Conditions of participation The requirements that a healthcare provider must meet to be able to bill a payor and be reimbursed by that payor for services rendered.

Contractors Centers for Medicare and Medicaid Services (CMS) primary third-party claims management entities which administer payments to facilities, physicians, and commercial laboratory providers according to national and local coverage determination policies; may also administer other elements of the Medicare program (e.g., NCCI, MolDx).

Contractor advisory committee (CAC) A committee established by a Medicare contractor to assist in development of local coverage determinations (LCDs).

Core Quality Measures Collaboration (CQMC) A broad-based coalition of healthcare organizations working to facilitate cross-payor measure alignment through the development of core sets of "meaningful measures" that are electronically available to assess the quality of healthcare in the United States; used by CMS in the National Quality Strategy.

Current Procedural Terminology (CPT) Proprietary service codes developed and maintained by the American Medical Association and required for filing claims and billing of Medicare and other third-party payors.

Custom panel Grouping of several independent codes made available as a single, orderable procedure, usually as an ordering convenience; generally billed as individual tests.

Department of Justice (DOJ) The federal entity responsible for enforcement of compliance with rules and regulation for laboratory claims.

Diagnosis-related groups (DRGs) Classification system developed at Yale that defines more than 700 major diagnostic categories and places patients into case types based on the ICD-CM classifications. Substantially updated in 2007 as MS-DRG (Medicare severity adjusted) and may include additional documentation of Complications and Comorbidities (CC) or Major Complications and Comorbidities (MCC).

Downcode The use of a lower-reimbursed test to induce unnecessary utilization.

Eliminating Kickbacks in Recovery Act (EKRA) Legislation passed in 2018 to strengthen controls against patient brokering and recovery profiteering by prohibiting accepting or paying kickbacks for referrals in recovery homes, clinical treatment facilities, or laboratories.

End-stage renal disease (ESRD) The term used for Medicare beneficiaries who have permanent kidney dysfunction requiring dialysis treatment.

Explanation of (medical) benefit form (EOB/EOMB) Provides reasons for denial of payment by a payor; known as a Medicare summary notice (MSN) for Medicare beneficiaries.

Food and Drug Administration (FDA) clearance/approval Assessment by the FDA that a test system meets specified performance criteria; failure to have required FDA clearance or approval for a particular test is generally justification for claim denial.

Fraud and abuse The receipt of payment for services that are not appropriate to the patient situation; generally results from the systematic application of incorrect coding approaches. Fraud is distinguished as being intentionally deceptive.

Government Accountability Office (GAO) Provides Congress, the heads of executive agencies, and the public with timely, fact-based, nonpartisan information that can be used to improve government and save taxpayers billions of dollars, including reports on laboratory test utilization.

Health Insurance Portability and Accountability Act of 1996 (HIPAA) Legislation that resulted in regulations to protect health insurance coverage for workers and their families when they change or lose their jobs, also required the Department of Health and Human Services to establish national standards for electronic healthcare transactions and national identifiers for providers, health plans, and employers and addresses the security and privacy of health data.

Healthcare Common Procedure Coding System (HCPCS) The code set recognized by federal and other third-party payors to describe medical, surgical, and diagnostic services. The CPT system is accepted as the HCPCS level 1 code set for laboratory and physician services.

Healthcare Effectiveness Data and Information Set (HEDIS) Monitors for effectiveness of healthcare under various payor plans, generally measures compliance with evidence-based guidelines; developed and maintained by the National Committee for Quality Assurance (NCQA).

Health Technology Assessment (HTA) group A group within an institution whose purpose is the systematic evaluation of properties, effects, and/or impacts of healthcare technology; includes medical, social, ethical, and economic dimensions, with the purpose to inform decision making in the health area including for laboratory medicine procedures.

Improper payment Payment made for a healthcare service that is not indicated based on documentation or clinical condition.

Inducement Offering incentives to nonfederal payors to encourage them to also submit federal program testing; a violation of the Stark legislation.

International Classification of Diseases, Clinical Modification A system for documenting clinical conditions and the reason for a patient encounter. The 9th edition (ICD-9-CM) was replaced by a substantially updated 10th edition (ICD-10-CM) in 2014 and will be replaced by ICD-11 in the near future.

International Classification of Diseases, Version 10, Procedure Coding System (ICD-10-PCS) Laboratory procedure coding system intended for use as an alternative to CPT; not currently in use.

本书版权归John Wiley & Sons Inc.所有

Kickback The provision of any item of value in exchange for referral of federal business to a laboratory; the Anti-Kickback Statute explicitly prohibits this practice.

Laboratory-developed test An assay developed by, validated by, and owned by a single laboratory; may use analyte-specific reagents (ASR) and be classified as a proprietary laboratory analysis (PLA) or advanced diagnostic laboratory test (ADLT).

Local coverage determination (LCD) A coverage policy developed by a local Medicare or other contractor through a standard process that defines the CPT codes covered for defined ICD-CM conditions; establishes "medical necessity" conditions.

Medicaid program Program established under Title XIX of the Social Security Act, which provides health insurance to indigent patients; the state and federal governments fund the program jointly.

Medical necessity The determination of ICD-CM codes for which a CPT code will be reimbursed as reasonable and necessary; if payment conditions are not met, considered "not medically necessary."

Medically unlikely edits (MUEs) Prepayment NCCI claim edits that assess whether an appropriate number of units of a single code have been filed on a claim, i.e., frequency edits.

Medicare Federally managed health insurance plan covering Americans over age 65 and Americans under age 65 who have certain disabilities and for most patients with ESRD; established by a 1965 amendment to the Social Security Act. There are several distinct components (Parts A, B, C, and D).

Modifier Two-digit numbers (CPT) or letters (HCPCS) that are appended to a specific CPT code prior to the billing process. Modifiers are "used to indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code."

National Correct Coding Initiative (NCCI) Listings of CPT codes that should not be used simultaneously due to a determination that their use is not in accordance with the intended use; updated quarterly by a Medicare contractor. Procedure-to-procedure (PTP) edits fall into two major categories: comprehensive/component and mutually exclusive. Edits also indicate the code pairs in these edit categories for which a modifier (generally -59) may be appropriate. Additional edits included frequency edits (medically unlikely edits [MUE]) and add-on code edits.

National coverage determination (NCD) A coverage policy developed by CMS through a standard process that applies to Medicare and Medicaid programs and defines the CPT codes covered for defined ICD-CM conditions; establishes "medical necessity" conditions.

National Healthcare Safety Network (NHSN) A widely used healthcare-associated infection tracking system from CDC; NHSN provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections.

National provider identifier (NPI) A unique 10-digit identification number issued to healthcare providers in the United States by the CMS.

"Neg Reg" Negotiated Rulemaking Committee for diagnostic clinical laboratory tests. The committee was charged with the development of national coverage determinations of medical necessity for select laboratory tests as a component of the Balanced Budget Act of 1997.

Office of Inspector General (OIG) An office of the Department of Health and Human Services responsible for oversight of programs for compliance with rules and regulations; issues reports including fraud alerts, advisory opinions regarding suspect practices including in laboratory billing.

Outcome assessment The process of determining whether a particular measure will have a positive clinical, and presumably financial, impact on patient care.

"Pay and chase" A strategy whereby reimbursement for services is made as quickly as possible and reviewed after the fact for appropriateness. If inappropriate, payback is required, and legal action is possible for fraud and abuse.

"Pay it right" A goal of CMS to "pay the right amount to the right provider for the right service to the right beneficiary."

Prior authorization A health plan cost-control process by which physicians and other health care providers must obtain advance approval from a health plan before a specific service is delivered to the patient to qualify for payment coverage; also known as precertification or prior approval.

Procedure-to-procedure (PTP) edits Prepayment NCCI claim edits that assess whether two codes are appropriate to file on a claim on the same date of service; there are two types: comprehensive or component code edits, and mutually exclusive edits.

Profit In general terms, revenues less expenses.

Profitability ratios Ratios that measure the combined effects of liquidity, asset management, and debt management policies on operating results, in general terms revenues/expenses.

Protecting Access to Medicare Act (PAMA) Legislation making significant changes to how Medicare pays for clinical diagnostic laboratory tests under the Clinical Laboratory Fee Schedule (CLFS). Effective 1 January 2018, the payment amount for most tests equals the weighted median of private-payor rates submitted by applicable laboratories. Payment rates under the private-payor rate-based CLFS are updated every 3 years.

Postpay audits A targeted evaluation of claims for accuracy and compliance with billing rules after payment has been made. Detected errors render payments already made subject to reimbursement.

Prepay edits Edits used for the systematic evaluation of claims for accuracy and compliance with billing rules prior to payment. Detected errors render the claim subject to denial.

Program integrity A systematic approach to prevention, detection, and correction of improper payments for healthcare services.

Quality program Developed by a payor to assess compliance with established metrics developed to assess quality of care.

本书版权归John Wiley & Sons Inc.所有

Reason codes The Claim Adjustment Reason Codes (CARC) are part of a national code set that identifies the reasons for any difference between the provider charge for a service and the payor's payment for a service. This code set is maintained by a national code maintenance committee.

Reasonable-charge methodology Based on inherent reasonableness, CMS authority to arbitrarily increase or decrease payment base.

Reflex test Second related, codeable test, which is performed automatically when initial tests are positive or abnormal.

Regulations Legally binding rules developed to implement a statute.

Remark codes The Remittance Advice Remark Codes (RARC) are used to convey information about remittance processing or to provide a supplemental explanation for an adjustment already described by a Claim Adjustment Reason Code (CARC). RARC codes are maintained by the CMS.

Social Security Act of 1967 Provided for healthcare benefits for "the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part" in the elderly and, subsequently, in disabled individuals.

Standards of conduct Standards should promote commitment to the accurate, ethical, and legal practice of laboratory medicine.

Standing order In laboratory medicine a test or test grouping routinely performed at a specified interval without a specific order.

Stark legislation Legislation prohibiting referral of designated health services including laboratory services to an entity with which an ordering provider has a financial relationship. Specific regulatory exceptions do exist.

Statute A law passed by the U.S. Congress or a state legislature.

Substantially in excess Defined as 120% of the average charge to all payors for each test; deemed by CMS to represent excessive payment.

Transmittal The mechanism by which the CMS conveys information regarding the Medicare program to providers and payors (e.g., national coverage determinations that have been updated with technical corrections).

Unbundling Coding individual tests rather than using an appropriate AMA panel approved for payment by the CMS; also known as "exploding charges."

United States Preventive Services Task Force (USPSTF) An independent appointed expert medical panel that systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services.

Upcoding Using a higher-paying code than justified to maximize reimbursement.

Value A measurable quality improvement as a result of expenditures (i.e., quality/cost).

REFERENCES

1. **Aldwell M**. 2003. Stem revenue losses with effective CDM management. *Healthc Financ Manage* **57**:84–88.

2. **Cathey R**. 2003. 5 ways to reduce claims denials. *Healthc Financ Manage* **57**:44–48.

3. **CMS**. 2001. Rules and regulations, Medicare program; negotiated rulemaking: coverage and administrative policies for clinical diagnostic laboratory services. *Fed Regist* **66**:58788–58890.

4. **Carter D**. 2002. Optimizing revenue by reducing medical necessity claims denials. *Healthc Financ Manage* **56**:88–94, 96

5. **American College of Radiology**. 2023. About the ACR Appropriateness Criteria. https://www.acr.org/Clinical-Resources/ACR-Appropriateness-Criteria/About-the-ACR-AC. Accessed 1 March 2023.

6. **CMS**. 2003. National Coverage Determination (NCD). Urine culture, Bacterial. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=25&ncdver=1. Accessed 8 April 2023.

7. **GAO**. 2003. Medicare: Divided Authority for Policies on Coverage of Procedures and Devices Results in Inequities. https://www.gao.gov/products/gao-03-175. Accessed 1 March 2023.

8. **Seifert O**. 2022. HTA bodies: what are they and why do they matter. The Evidence Base On-line. https://www.evidencebaseonline.com/hta-bodies-what-are-they-and-why-do-they-matter/. Accessed 1 March 2023.

9. **Federal Register**. 1995. Medicare program; criteria and procedures for extending coverage to certain devices and related services—HCFA. Final rule with comment period. *Fed Regist* **60**:48417–48425.

10. **Federal Register**. 1997. Medical devices; classification/reclassification; restricted devices; analyte specific reagents—FDA. Final rule. *Fed Regist* **62**:62243–62260.

11. **Klein RD**. 2020. Current policy changes in genomic medicine. *Clin Chem* **66**:61–67.

12. **Cohen P**. 2022. The time is now for laboratory benefit management. *Manage Health Exec* **32**:5–6.

13. **Borden A**, **Showalter D**, **Storchan G**, **Hughes K**. 2015. The diagnosis for diagnostics: changes to Medicare payment and coverage of clinical laboratory tests. *Am J Manag Care* **21**(SP12):407–408.

14. **Sireci AN**, **Patel JL**, **Joseph L**, **Hiemenz MC**, **Rosca OC**, **Caughron SK**, **Thibault-Sennett SA**, **Burke TL**, **Aisner DL**. 2020. Molecular pathology Economics 101: an overview of molecular diagnostics coding, coverage, and reimbursement. *J Mol Diagn* **22**:975–993.

15. **Ridge JR**, **Statz S**. 2015. Exact sciences' experience with the FDA and CMS parallel review program. *Expert Rev Mol Diagn* **15**:1117–1124.

16. **Novitas**. 2022. Bill infectious disease panels correctly. https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00270304. Accessed 15 October 2023.

17. **CMS**. 2023. Billing and coding: Respiratory pathogen panel testing (A58575). https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=58575. Accessed 8 April 2023.

本书版权归John Wiley & Sons Inc.所有

18. **Parker S**, **Davidson N**, **Gagliano R**. 2002. Preventing & dealing with ESRD claim denials. *Nephrol News Issues* **16**(18–21):25–26.

19. **Matters MLN**. 2020. FAQs on the 3-day payment window for services provided to outpatients who are later admitted as inpatients. https://www.cms.gov/files/document/se20024.pdf. Accessed 8 April 2023.

20. **Scott M**, **Nguyen D**. 2009. Clinical laboratory compliance: something old, something new. *Lab Med* **40**:428–435.

21. **Matters MLN**. 2008. Remittance advice remark code (RARC) and claims adjustment reason code (CARC) update. https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/mm6229.pdf. Accessed 8 April 2023.

22. **X12**. 2022. Claims adjustment reason codes. https://x12.org/codes/claim-adjustment-reason-codes. Accessed 8 April 2023.

23. **X12**. 2023. Remittance advice remark codes. https://x12.org/codes/remittance-advice-remark-codes. Accessed 8 April 2023.

24. **Mesaros F**. 2000. The remittance advice, auditing for compliance. *Clin Leaders Manga Rev* **14**(2):69–71.

APPENDIX 34.1 General References and Resources

CPT manual, current professional edition, *current edition* (issued by AMA every October, effective 1 January)

CPT Changes (current year). An Insider's View (AMA Press, Chicago, IL)

HCPCS Level II manual, current edition (issued every January and effective upon issuance)

ICD-10-CM manual (issued every October and effective upon issuance)

Medicare Clinical Laboratory Fee Schedule (issued every November and effective 1 January)

Medicare Physician Fee Schedule (issued every November and effective 1 January)

National Correct Coding Policy Manual, *Chapter X—Pathology and Laboratory Services,* current version (issued quarterly and effective upon issuance)

Codemap (subscription service available at http://www.codemap.com; accessed 12 April 2023)

HCPro store (compliance and documentation subscription services available from HCPro at https://hcmarketplace.com/; accessed 12 April 2023)

The Dark Report (subscription service available at https://www.darkintelligencegroup.com/; accessed 12 April 2023)

Washington G2 Intelligence Reports (subscription services available at https://www.g2intelligence.com/; accessed 12 April 2023)

本书版权归John Wiley & Sons Inc.所有

APPENDIX 34.2 Websites

American Medical Association (AMA) CPT Resources

https://www.ama-assn.org/amaone/cpt-current-procedural-terminology (accessed 12 April 2023)

CPT Coding Resources

https://www.ama-assn.org/practice-management/cpt/need-coding-resources (accessed 12 April 2023)

Centers for Medicare and Medicaid Services
http://www.cms.gov (accessed 12 April 2023)

Appropriate Use Criteria

https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/appropriate-use-criteria-program (accessed 12 April 2023)

Clinical Laboratory Fee Schedule

https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinicallabfeesched (accessed 12 April 2023)

CMS Transmittals

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals (accessed 12 April 2023)

Forms

https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List (accessed 12 April 2023)

ICD-10 Resources

https://www.cms.gov/Medicare/Coding/ICD10 (accessed 1 March 2023)

Medicare Coverage Database

https://www.cms.gov/medicare-coverage-database/search.aspx (accessed 1 March 2023)

Medicare Internet-Only Manual

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs (accessed 12 April 2023)

Medicare Learning Network (instructional resources for Medicare billing)

https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlngeninfo (accessed 1 March 2023)

MolDx

https://www.palmettogba.com/moldx (accessed 12 April 2023)

National Correct Coding Initiative Edits

https://www.cms.gov/medicare-medicaid-coordination/national-correct-coding-initiative-ncci/ncci-medicare (accessed 12 April 2023)

National Quality Strategy

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy (accessed 12 April 2023)

Core Quality Measures Collaborative

https://www.qualityforum.org/cqmc/ (accessed 12 April 2023)

Protecting Access to Medicare Act (PAMA)

https://www.cms.gov/medicare/clinical-laboratory-fee-schedule/clfs-pama-educational-resources (accessed 12 April 2023)

Physician Fee Schedule

https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched (accessed 1 March 2023)

College of American Pathologists (CAP)
http://www.cap.org (accessed 1 March 2023)

Coding and Payment Resources

https://www.cap.org/member-resources/practice-management/coding-and-payment (accessed 12 April 2023)

Department of Justice
https://www.justice.gov/ (accessed 12 April 2023)

Healthcare Fraud Unit

https://www.justice.gov/criminal-fraud/health-care-fraud-unit (accessed 12 April 2023)

Government Accountability Office (GAO)
https://www.gao.gov/ (accessed 12 April 2023)

Food and Drug Administration (FDA)
https://www.fda.gov/ (accessed 12 April 2023)

Overview of IVD

https://www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation (accessed 12 April 2023)

Logical Observation Identifiers, Names, and Codes (LOINC)
https://loinc.org/ (accessed 12 April 2023)

National Academy of Medicine (previously Institute of Medicine)
https://nam.edu/ (accessed 12 April 2023)

Office of Inspector General (OIG)
https://oig.hhs.gov/ (accessed 12 April 2023)

Laboratory compliance program guidance

https://oig.hhs.gov/authorities/docs/cpglab.pdf (accessed 12 April 2023)

Special fraud alerts, bulletins and other guidance

https://oig.hhs.gov/compliance/alerts/ (accessed 12 April 2023)

SNOMED
https://www.snomed.org/ (accessed 12 April 2023)

United States Preventive Services Task Force (USPSTF)
https://www.uspreventiveservicestaskforce.org/uspstf/ (accessed 12 April 2023)

本书版权归John Wiley & Sons Inc.所有

35

Reimbursement Compliance

Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

Introduction
Improper Payments
Program Integrity
Authority for Program Integrity • Activities in Program Integrity
Payor Integrity
Prepayment Review • Postpayment Review
Laboratory Provider Integrity
The Seven Essential Elements • Specific Areas of Concern
Coding and Billing Issues
CPT Coding • Modifiers • ICD-CM Coding • The Requisition • Special Ordering Situations
Medical-Necessity Issues
Record Retention
Marketing Practices
Pricing and Inducements • Ordering Provider and Patient Communication
Fraud Alerts and Advisory Opinions
Auditing and Monitoring
Response to Possible Fraud or Abuse
Laboratory Examples of Fraud and Abuse
SUMMARY
KEY POINTS
GLOSSARY AND APPENDIXES
REFERENCES

OBJECTIVES

To describe what constitutes fraud and/or abuse

To discuss specific examples of the most common forms of fraud and abuse found in the public and private sectors

To discuss a prepayment review and its relationship to reimbursement

To describe some of the legal ramifications that might be associated with a postpayment audit

To define the seven key elements within a sound compliance program

To list some of the acceptable marketing practices, as well as some that may not be in compliance

To provide several specific examples of potential laboratory fraud and abuse

Money made through dishonest practices will not last long.

Chinese proverb

With the extensive array of statutory, regulatory, and other payor-defined rules that exist with regard to billing for healthcare services, including laboratory medicine, it is no surprise that improper payments are not uncommon. Improper payments may be either over or under the appropriate amount, and they may result from actions on the part of the provider or a provider's contracted billing entity or the payor. To minimize and control improper payments, including those that are intentional and therefore potentially fraudulent, all entities involved in reimbursement should have formal review processes in place. Collectively these processes are referred to as a "compliance program." The most extensive review program encountered in the laboratory is that developed by the federal government under the heading of "program integrity." A strong compliance program uses a systematic approach for prevention, detection, and correction of improper payments for healthcare services to preserve the integrity of the provision of healthcare services. In laboratory medicine, program integrity includes elements that ensure both accurate billing by the laboratory and accurate payment by the payor. Compliance expectations modeled after the federal program exist for essentially all third-party payors to ensure that appropriate payment is made for covered services but not made for noncovered services.

Reader please note that the Glossary and Appendixes for the three chapters in this section are combined and provided at the end of chapter 34.

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch35.

本书版权归John Wiley & Sons Inc.所有

Improper Payments

Improper laboratory payments are payments made to a laboratory provider for testing that was not indicated based on the documentation provided, including the test codes submitted or the clinical condition of the patient. Improper payments can be categorized as errors, waste, abuse, or fraud (Fig. 35.1). Errors generally result from simple mistakes in completing documentation on the requisition or claim form or from unintentionally assigning an incorrect code for the procedure or the diagnosis. Waste generally results from inefficient practices leading to overutilization or in some cases from performing medically unnecessary testing. Abuse can be considered as "bending the rules" and generally results from improper billing practices. This can include a wide range of behaviors, including but not limited to billing for a noncovered service, misusing codes on a claim out of compliance with coding conventions (e.g., upcoding or unbundling), and inappropriately allocating costs on a cost report (e.g., for diagnosis-related group submission). While these types of activities are not acceptable, and any payment deemed inappropriate should be refunded, they are not considered fraudulent. Fraud is distinguished on the basis of intent. Thus, laboratory fraud may be defined as the intentional deception or misrepresentation of documentation on a claim to purposely receive reimbursement for services not performed, not necessary, or performed at a higher level or frequency or including more units of service than appropriate. Fraud may also result from certain business arrangements that may lead to inappropriate utilization of and overpayment for services. Fraudulent activities are frequently systematic and may result in significant amounts of improper payment.

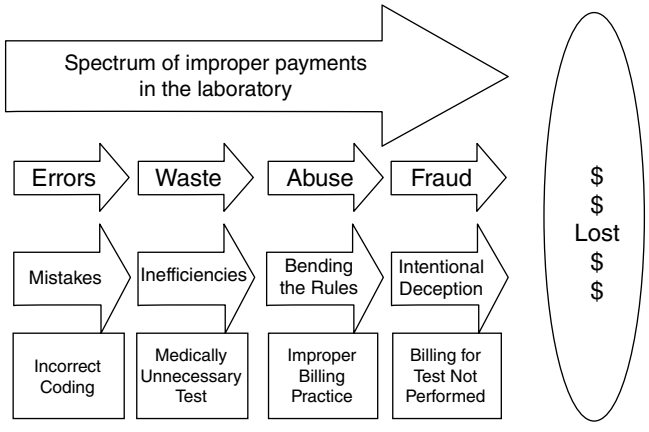


Figure 35.1 Program integrity activities focus on prevention and detection of improper payments resulting from a spectrum of related coding and billing activities (adapted from https://www.cms.gov/medicare/medicaid-coordination/healthcare-fraud-prevention-partnership).

Claim review processes will identify many unintentional errors, particularly those pertaining to inadequate documentation. However, for several decades now, the laboratory medicine industry has been the subject of intense scrutiny for evidence of systematic attempts to receive improper payment (1), an effort which intensified recently focusing on toxicology, COVID-19-related, and molecular genetic testing (2). A systematic process of receiving inappropriate payment is often referred to collectively as "fraud and abuse." Identification of fraud and abuse may result in criminal and civil liabilities as well as payback of amounts determined to be paid in error by both federal payors and private third-party insurers. However, it is important to recognize that innocent errors and mistakes do occur. Only in the case of actual knowledge of the falsity of a claim, reckless disregard of the truth of the claim, or deliberate ignorance of the correct process will civil or criminal legal action be taken. Truly innocent false or incorrect claims generating overpayment are generally simply subjected to repayment.

Both private insurers and federal payors have identified situations that are associated with fraud and abuse. These activities include the following (3):

- *Providing an incorrect diagnosis or misrepresenting the diagnosis to justify payment*. This is known as "code jamming" (i.e., inserting a code that was not provided by the ordering provider but that will justify payment). Another practice is "code steering" (i.e., providing lists of diagnosis codes that are known to justify payment).
- *Billing for services not performed as ordered*. Performing and billing for tests not ordered is a straightforward incorrect practice as is billing for tests ordered but not performed at all (termed "sink testing"). Performing a related test for which the Current Procedural Terminology (CPT) code pays at a higher level is also incorrect (termed "upcoding") and performing tests that pay at a lower level (termed "downcoding") may be viewed as inducement to obtain additional business.
- *"Unbundling" or "exploding" charges by billing for individual codes rather than using a Centers for Medicare and Medicaid Services (CMS)-approved comprehensive or panel code or routinely billing mutually exclusive codes*. The National Correct Coding Initiative (NCCI) has been previously discussed (chapter 34) as a system by which all federal claims are subjected to a prepay review process to identify incorrect use of codes as described above. The correct use of "comprehensive" codes rather than "unbundled" individual codes, the routine "bundling" of codes and attaching them to a specific orderable code absent evidence of the medical appropriateness of doing so and with the knowledge and approval of the ordering

本书版权归John Wiley & Sons Inc.所有

providers that it is being done, and the routine use of mutually exclusive codes with modifiers to bypass edits absent the same criteria for medical appropriateness and with provider knowledge and approval are all considered suspect.

- *Referral of testing to a laboratory facility in which the ordering provider has a financial interest*. Legislation known as the Stark Law generally disallows billing for services performed in a laboratory in which a provider or an immediate family member has a financial interest. There are some clearly defined exceptions that allow billing, but self-referral arrangements are highly suspect and intensely scrutinized.
- *Routine waiver of deductibles and copayments on non-Medicare patients or offering charges lower than accepted market value*. Any attempt to offer incentives to nonfederal payors to encourage them to also submit federal program testing is termed "inducement" and is a violation of elements of the Stark legislation, the federal Anti-Kickback Statute, and more recently the Eliminating Kickbacks in Recovery Act (EKRA). "Downcoding" to encourage utilization is similarly inappropriate. The Office of Inspector General (OIG) looks closely at the common practice of laboratory discounts to determine if the Medicare program payment amounts are excessive relative to the charges to a laboratory's other clients.
- *Soliciting, offering, or receiving a kickback in exchange for receiving business*. The provision of any item of value in exchange for referral of federal business to a laboratory is also prohibited as a violation of elements of Stark and anti-kickback legislation. The provision of free testing services to clients (termed "professional courtesy"), free supplies other than those used strictly in the provision of laboratory services, and free data summary reports used for purposes other than evaluation of laboratory utilization (e.g., antibiograms, drug-of-abuse profiles) are unacceptable practices. Also suspects are clinical trial work done for no charge and routine leasing of laboratory space, primarily for specimen collection by a laboratory-affiliated phlebotomist, at rates higher than usual market rates. One can say that any value-added service has value and should therefore be billed to the client at a fair market price. There are some well-defined exceptions to the Stark Law, termed "safe harbors." These exceptions are particularly important in the provision of electronic health record (EHR) systems for test ordering and result transmission.

Many specific examples of situations involving these and other practices have been identified through review processes under program integrity and are often detailed in documents available from the OIG and CMS.

Program Integrity

Simply stated, the goal of program integrity is to "pay it right." That is, the goal is to pay the right amount to the right provider for the right service for the right beneficiary. Provisions to address the issue of program integrity in federal programs can be found in a number of statutes and resulting regulations.

Authority for Program Integrity

A primary basis for Medicare program integrity lies in provisions of the Social Security Act and CMS interpretation of resulting regulations. Services that are authorized by law are those described in Section 1828(a) (1)(A), which states that Medicare will pay for services "that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." This provision has been interpreted to indicate that preventive services are in general not covered except as defined by statute or CMS rulings. This phrase is also the basis for the development of medical-necessity rules for reimbursement. Medicaid and Children's Health Insurance Program (CHIP) coverage is generally based on criteria established by states administering the program, and other third-party payors establish their own coverage criteria, but in all cases the Medicare system frequently serves as a model. Failure to comply with and abide by the rules established by any payor may put a laboratory at risk for legal action.

To enforce compliance with government rules and regulations for federal reimbursement for healthcare services, in 1981 Congress enacted the Civil False Claims Act and the Civil Monetary Penalties Law. These laws authorized the Secretary of Health and Human Services (HHS) to impose civil monetary penalties (CMPs) for knowingly violating Medicare rules and regulations to receive improper payment from the federal government for services. In addition, the Secretary could specifically exclude an individual or entity determined to be in violation from participation in providing services to and receiving payment for federal program beneficiaries for designated periods. In 1994, the responsibility for enforcing Medicare statutes was realigned between both the CMS (the Health Care Financing Administration, HCFA, at that time) and the OIG. The HCFA (CMS) was given responsibility for program compliance, and the OIG was given responsibility for CMPs involving fraud and abuse. Finally, in 1996, the Health Insurance Portability and Accountability Act (HIPAA) increased maximum CMPs from $2,000 to $10,000 per item or service in noncompliance and increased assessments from two times to three times the amount claimed. HIPAA also established a formal Health Care Fraud and Abuse Control Program to combat such activities in claims filed by both public and private payors. It is noteworthy that HIPAA also paved the way for

本书版权归John Wiley & Sons Inc.所有

better enforcement of billing compliance for non-Medicare payors. Over the ensuing years, government efforts to ensure program integrity have continued to expand as have efforts by other payors.

Additional pieces of legislation that are important for program integrity are the Anti-Kickback Statute from 1987 and the physician self-referral laws known as the Stark Law initially passed in 1989. The Anti-Kickback Statute makes it a criminal offense to knowingly offer, pay, solicit, or receive any type of payment as an inducement or reward for referrals of items or services payable by a federal healthcare program. The Stark Law prohibits physician referral for designated healthcare services performed by an entity in which the physician or an immediate family member has a financial interest. The intent of both is to ensure that business practices do not allow for improper payments. More recently, the Eliminating Kickbacks in Recovery Act (EKRA) legislation in 2018 (4) was enacted to further strengthen protections against Illegal patient referrals by all providers. Although initially targeting drug testing programs, EKRA has been more broadly applied, including in COVID-19 recovery efforts related to medically unnecessary add-on testing such as additional individual respiratory tests, respiratory pathogen panels, genetic tests, and allergy tests (2).

It should also be noted that the CMS has the authority and responsibility under the Clinical Laboratory Improvement Amendments (CLIA) to ensure compliance by registered laboratories with all applicable federal rules and regulations. On a yearly basis, the CMS makes publicly available a listing of laboratory providers who have failed to comply with regulations pertaining to billing and reimbursement. The listing includes those laboratory providers to which the following apply:

- They have been convicted of fraud and abuse under federal or state laws.
- They have appeals and hearings pending for the same.
- They have been excluded from participation in federal programs.
- CMPs have been imposed on them.

Also under HIPAA's Privacy Rule is the authority to perform automated tracking. Complaints, incidents, allegations, investigations, and dispositions logged by any beneficiary or participant in a federal program can be tracked by CLIA number to generate provider-specific data. Automated tracking is recognized as an extremely important strategy for the future, and such efforts have been greatly enhanced under the Affordable Care Act. Systematic, electronic analysis and tracking has the potential to move efforts to reduce improper payments away from dependence on recovery to an early detection and proactive prevention approach.

In sum, there are numerous lines of authority that govern and enforce compliance with billing and reimbursement statutes and regulations. The lines are well established, and specific entities, primarily the CMS and the OIG together with the Department of Justice (DOJ), carry the authority to require payback and to impose both civil and criminal penalties as appropriate to the situation. The Government Accountability Office (GAO) considers healthcare programs to be high risk for improper payment, including fraud, since payments are generally made to "any willing provider" and are made in a relatively timely manner (5, 6). These features lead to a "pay and chase" approach to dealing with improper payments. However, new program integrity enforcement and monitoring enhancements are being added on a regular basis, and such programs apply not only to federal payor programs but also to private payors. In any case, if judged by indictments and payments, program integrity efforts may be deemed highly successful. The most recent Healthcare Fraud and Abuse Annual Report for 2021 noted more than 5 billion dollars in healthcare fraud and abuse settlements. The DOJ opened 831 criminal investigations with 312 convictions plus 805 new civil suits. In addition, the OIG investigations resulted in 504 criminal actions and 669 civil actions involving federal payments, and exclusion of 1,689 individuals from participation in federal healthcare programs (7). While these are not all related to laboratory payment issues, the laboratory remains a target in many investigations (8).

Activities in Program Integrity

Given the importance of program integrity, it is not surprising that the federal and state governments as well as other third-party payors have a number of programs in place to prevent, detect, and correct improper payments. Several entities are involved in ensuring program integrity for the CMS healthcare programs and are outlined in Table 35.1. In 2010, the CMS created the Center for Program Integrity to serve as a focal point for all activities pertaining to Medicare, Medicaid, and CHIP programs. However, well before that date a number of ongoing activities were in place. Contractors who administer benefits have extensive medical review programs in place that evaluate both prepay and postpay situations. In addition, several other contractor-directed programs are in place to address program integrity issues. For example, prepay issues have been regularly addressed by the NCCI contractor through quarterly update of edits since 1996.

Postpay concerns have been addressed through several programs. The Comprehensive Error Rate Testing (CERT) program was established in 2000. In this program, a designated contractor has responsibility for the random review of selected claims processed by federal payors to verify that contractor decisions are accurate and based on sound policy compliant

本书版权归John Wiley & Sons Inc.所有

Table 35.1 Government payor program integrity activities

Abbreviation	Entity or program	Prepay or postpay	Activities
CERT	Comprehensive Error Rate Testing	Postpay	CMS program to collect and review data on statistically valid random samples of fee-for-service claims to produce annual improper payment rates
CPI	Center for Program Integrity	Both	CMS coordinating center for all activities pertaining to prevention, detection, and recovery of improper payments
GAO	Government Accountability Office	Both	The investigative arm of Congress charged with examining matters pertaining to receipt and payment of public funds; has published a number of reports on government healthcare spending
HEAT	Health Care Fraud Prevention and Enforcement Action Team	Both	HHS and DOJ collaborative program to prevent waste, abuse, and fraud in Medicare and Medicaid programs; uses a multiagency Medicare Fraud Strike Force team in selected cities
MIC	Medicaid Integrity Contractors	Both	Contractors assigned to identify cases of suspected improper payments and take appropriate action in the Medicaid program
MR	Medical review	Both	Targeted review by a contractor to assess claim and payment accuracy that may result in corrective action or lead to a formal payment policy
NCCI	National Correct Coding Initiative	Prepay	CMS program designed to identify procedure code pairs that are not generally used together and to establish frequency limits on codes
OIG	Office of Inspector General	Both	Responsible for protecting the integrity of HHS programs by developing policy guidance documents and through a system of audits, investigations, inspections, and reports of findings; also maintains a list of individuals and entities excluded from CMS payment programs due to misconduct
PERM	Payment Error Rate Measurement	Postpay	CMS program to collect and review data on statistically valid random samples of state Medicaid and CHIP claims to produce annual improper payment rates
PSC	Program Safeguard Contractors	Postpay	Contractors assigned to identify cases of suspected improper payments and take appropriate action; similar to the ZPIC program
RAC	Recovery Audit Contractors	Both (initially postpay)	Contractors assigned to systematically identify and correct improper payments
ZPIC	Zone Program Integrity Contractors	Postpay	Contractors assigned to identify cases of suspected fraud and take appropriate action; similar to the PSC program

with statutes and regulations. The goal is to generate national paid claim error rates, claim processing error rates, provider compliance rates, and benefit-specific error rates. The purpose is to provide benchmark data that can be utilized to identify emerging trends and implement effective corrective action. A similar program, the Payment Error Rate Measurement (PERM), was implemented for Medicaid and CHIP data analysis in 2006.

For focused review of provider payments, Program Safeguard Contractors were engaged in 2003 to assume formal responsibility for the Medicare Integrity Program. These contractors were charged with identifying and reviewing any suspected case of improper payments. A related entity, Zone Program Integrity Contractors (ZPIC), focuses specifically on suspected fraud cases, and Medicaid Integrity Contractors (MIC) focus on issues regarding payment in that program. A final group, Recovery Audit Contractors (or Recovery Auditors), was initially established in 2003 as a pilot program and subsequently extended nationally in 2010. These contractors identify both overpayment and underpayment and refer providers to the appropriate administrative contractor for action.

Finally, it should be noted that there are other significant contributors to program integrity. In 2009, the Health Care Fraud Prevention and Enforcement Action Team (HEAT) was developed as a joint effort by DOJ and HHS to evaluate potential improper payments in selected cities. The GAO plays a role in developing reports on healthcare spending to identify potential problem areas, and of course, the OIG facilitates all program integrity efforts. Medicare even solicits assistance from beneficiaries to identify questionable reimbursement situations through a number of mechanisms. Recently, the National Fraud Prevention Partnership was announced to engage a variety of public and private entities in sharing information to stop losses to payors, including patients, before they occur (9).

To ensure continuing emphasis on areas considered at risk for improper payment, the OIG publishes an annual Work Plan (10) that describes audits and evaluations planned for a number of federal entities, including those

本书版权归John Wiley & Sons Inc.所有

making federal healthcare payments. In addition, the OIG publishes an annual Compendium of Unimplemented Recommendations, i.e., audits and evaluations proposed but not yet implemented (11), to reduce fraud, waste, and abuse in HHS programs.

Payor Integrity

While much of the focus has been on laboratory provider error in the claim submission process, contractors or third-party insurers paying claims also have an absolute obligation to develop effective medical review processes. In fact, contractors have on occasion been found to be responsible and liable for payment errors. There are two main categories of review processes that must be developed and implemented by the administrative contractors: those performed prepayment and those performed postpayment.

Prepayment Review

Prepayment review is the preferred approach for a very obvious reason. It eliminates the need to "pay and chase," i.e., attempt to recoup payments made in error. Prepayment review is ordinarily accomplished through a computer-based system of defined edits similar to those used by laboratory providers to submit "clean claims." Prior to payment, claims are assessed for complete documentation, correct coding, and evidence of medical necessity (i.e., meets criteria as a covered service). As already discussed (chapter 34), a variety of edits are currently in place and include those published as frequency limits, NCCI edits, national coverage determinations (NCDs), and local coverage determinations (LCDs). In a small percentage of cases, claims may be manually reviewed to ensure that the edit process is correct, and medical record documentation may be requested from both the ordering provider and the laboratory provider. In addition, any laboratory provider that has been identified as having problems with correct claim submission may be placed on routine prepayment review status.

Postpayment Review

Postpayment review is also an important component of the claim review process. This process focuses on statistical evaluation of subsets of claims (i) to check claims on a random basis to function as a deterrent for fraud and abuse, (ii) to identify aberrant patterns of utilization and billing that may indicate a general emerging or provider-specific problem, and (iii) to determine the extent of a particular kind of problem that has been previously identified. When a review is performed to detect aberrancies or specific problems for a particular laboratory or other healthcare provider, it is termed a focused medical review. In turn, a focused medical review may identify a problem that results in the development of a prepayment LCD.

Postpayment review may be performed on individual claims or on samples of claims. From review of a statistically valid sample, the payor can estimate the extent of incorrect payment made without necessarily undertaking a complete medical record review. However, the possibility exists that complete evaluation of all individual documentation associated with testing may be performed whenever a postpayment review identifies a significant problem associated with large expenditures.

Laboratory Provider Integrity

While payors have an obligation to "pay it right," laboratory providers obviously have an obligation to "do it right" in the first place. The continuing recognition of costly systematic billing errors, including some categorized as fraudulent, led the OIG to issue the Compliance Program Guidance for Clinical Laboratories in August 1998 (12). This document, which updated the previous Model Clinical Laboratory Compliance Plan published by the OIG in 1997, is designed primarily to ensure that appropriate reimbursement is made through federal programs, that is, to ensure that payors "pay it right." However, it also provides commonsense principles for conducting laboratory business in general by promoting the concept of "doing it right." The document provides guidance for "doing the right thing" (through compliance with all regulatory and statutory rules and regulations), for "getting paid for doing the right thing" (through correct coding and billing practices), and for "making sure the right thing is done" (through a systematic approach to ensuring that rules and regulations are followed). Although issued almost 25 years ago, this document still forms the basis for ongoing laboratory compliance efforts.

While the 1998 guidance is voluntary, the strategies recommended represent sound business practices and serve to make certain that laboratories function as business entities providing laboratory services in an ethical and legal manner. The importance of a compliance program has recently been affirmed in the 2010 Patient Protection and Affordable Care Act (PPACA or ACA) provisions that require the Secretary of HHS to promulgate "core elements" and set an effective date for mandatory compliance programs. The core elements were not specified but are assumed be similar to those in the 1998 guidance. They will presumably be defined through a rulemaking process, but the legislation did not set a deadline for these actions. ACA provisions also increased monies for activities related to program integrity, for example, ramped-up computer capabilities to support proactive data analysis and systematic audits. Under the ACA-required revalidation process, laboratories are classified as moderate risk, so unannounced on-site visits to ensure compliance programs are operational may occur.

本书版权归John Wiley & Sons Inc.所有

A strong foundation for an effective compliance program requires that a laboratory provider have understandable and updated compliance program policies. These policies should follow the recommendations and address the situations discussed in the 1998 OIG guidance and any ACA-driven core elements and should apply equally to all payor types. The compliance program should be comprehensive and address all relevant aspects of preanalytical, analytical, and postanalytical processes (13). The laboratory must also be in compliance with all other applicable federal, state, and local statutes and regulations (e.g., CLIA, the Occupational Safety and Health Act, HIPAA) (14). Laboratories are in a truly unique position to provide essential information on appropriate testing to ordering providers, and rather than being a burden, a sound compliance program can be thought of as an opportunity to provide such information (15).

The Seven Essential Elements

The OIG compliance guidance specifies that, at a minimum, a sound compliance program should include seven key elements (12). These are as follows:

- *There should be written standards of conduct*. These standards should promote the laboratory's commitment to the accurate, ethical, and legal practice of laboratory medicine.
- *There should be a chief compliance officer (CCO) charged with procedure and protocol development, education and training, and auditing and monitoring*. The CCO should interact with a formal corporate (or institutional) compliance committee (CC) composed of key individuals who are charged with approval of compliance policies and with oversight of all other elements of the compliance program. Both the CCO and the CC should report directly to the chief executive officer.
- *There should be an effort to provide standardized education about compliance*. Compliance training should be a mandatory component of an employee's initial orientation as well as the annual competency assessment process.
- *There must be a defined process for receipt and documentation of complaints, including an opportunity for anonymity, if desired, via a hotline*. The system must be clearly understood by associates and information on reporting readily available.
- *There must be a system to respond to allegations of possible fraud or abuse, as well as disciplinary policies that clearly delineate consequences for violations of compliance policies*. It is expected that a zero-tolerance approach to violations will be taken.
- *The compliance program must include the use of ongoing monitoring and auditing tools to detect possible compliance problems as soon as possible and to measure the effectiveness of interventions designed to minimize the occurrence of such problems*. A system of ongoing monitors and periodic audits should be clearly defined in laboratory policies, including benchmark performance metrics and the corrective action process when out of compliance.
- *The program must specify the processes for remediation of identified systemic problems and address individuals or other business associates who are sanctioned from participation in federal programs due to a known previous violation*. Policies for documentation of corrective action and human resource policies must be in place to ensure that appropriate actions are taken.

The laboratory must have representatives drawn from the technical side of operations to address scientific and medical concerns in policy development and assessment. On the business side, individuals who are involved in management, marketing, client services, coding, billing, accounts receivable, and medical records are equally important contributors to an effective compliance program.

Specific Areas of Concern

To guarantee that the overall goals of the above elements are met, there are a number of specific areas that the OIG guidance identifies as critical to address (16). Each area should ideally be discussed in a specific compliance policy, with protocols or procedures for implementing the policies developed for each. In addition, each policy area should be specifically monitored using defined audit criteria. Table 35.2 provides a listing of areas commonly requiring compliance policy development. However, these may be divided into five main general areas of concern:

- Coding and billing issues
- Medical-necessity issues
- Record retention
- Marketing practices
- Compliance with OIG and CMS compliance issuances

Coding and Billing Issues

Key to any successful compliance program is a clear understanding of the principles of procedure coding as well as the accurate and complete application of those principles (chapter 31). The laboratory should be familiar with the HIPAA standard data sets, particularly those used for billing. These include CPT codes, International Classification of Diseases, Clinical Modification (ICD-10-CM and soon ICD-11-CM) codes, diagnosis-related groups, ambulatory payment classifications, revenue center and provider type codes, and remittance advice codes.

本书版权归John Wiley & Sons Inc.所有

Table 35.2 Summary of areas requiring compliance policies

ABN
Ambiguous test orders
Anonymity and nonretribution
Billing for calculations
Claim submission, postsubmission review of EOMBs
Claim submission, presubmission review
CLIA regulations
Client contracts
Client supplies, provision of and monitoring
Confidentiality of medical information
Contracts with third-party billing companies
Cost reporting, laboratory component
Courier service
CPT coding
Custom panels and physician acknowledgment
Data summaries as a free service
Diagnosis information, translation to ICD-10 codes
Discounts and special prices
Education and training for customers as inducement
Employees, phlebotomists in client offices
ESRD arrangement
Excused charges and adjustments
Fraud alerts, review and compliance
Gifts, contributions, and entertainment
Health fairs as inducement
Home health service client arrangements
ICD-10 codes, obtaining and using
Indigent care
Medical-necessity guidelines
Monitoring utilization of laboratory services by clients
Nonemployment of sanctioned individuals
Notices to physicians
Nursing home client arrangements
OSHA regulations
Placement of equipment or products in client offices
Professional courtesy
Record retention
Reflex testing
Release of test results by phone, fax, and/or other nonroutine methods
Removal of hazardous waste for clients as inducement
Rental or lease of space from healthcare providers
Reporting compliance issues and open-door policy
Requisition design
Sales and marketing
Sales proposals
Standing orders
Test not ordered and/or not performed
Test ordering by authorized individual
Test orders, requisitions, and electronic order review
Verbal and add-on test orders

CPT Coding

The laboratory must have access to a current copy of the American Medical Association (AMA) CPT codebook as well as to current supplementary Healthcare Common Procedure Coding System (HCPCS) codes. A comprehensive annual review of procedure coding must be conducted to ensure that additions, deletions, and modifications made by the CPT editorial panel and published by the AMA each fall are incorporated by the laboratory into the current recommended coding by January 1. This also provides an opportunity to ensure that previous code selections are compatible with coding convention and reimbursement rules. All associated documents such as requisitions (manual forms and online order entry), service manuals, charge masters, and fee schedules must also be updated to reflect any changes. It is also recommended that at the time of the annual CPT review, laboratories review and update their cost analyses for use in setting laboratory charges for procedures. In November, the CMS generally publishes a transmittal that sets the national limitation amounts (NLA) for Medicare reimbursement of each CPT code, thus allowing revenue projections to be made for budget purposes. Note that the NLA is now based on amounts set by the process set forth in the Protecting Access to Medicare Act (PAMA, discussed in chapter 33). Of course, it is absolutely essential that all parties in the billing process be informed of any coding or charging changes.

Modifiers

The laboratory has the responsibility for the appropriate use of modifiers, both AMA-approved and HCPCS-based. In general, these are added at the time of billing. However, it is up to the laboratory to review coverage rules and edits to determine when use of a modifier is indicated. The most common modifiers used are those that designate advance beneficiary notice (ABN) status (GA, added to claims with a properly executed ABN in the file; GY, added to claims in which the item or service is statutorily excluded; and GZ, added to claims in which the item or service is expected to be denied as not reasonable or necessary and there is not a properly executed ABN in the file), those that designate replicate use of a code (-59 and -91), one that indicates CLIA-waived status (QW), and the referred test modifier (-90).

ICD-CM Coding

ICD-CM codes are updated twice per year and published annually. While the ordering provider rather than the laboratory provider selects diagnostic codes used for a test order, it is still necessary that the laboratory maintain updated data files for claim review. In addition, laboratories do have the authority to translate a narrative code provided on a requisition into an ICD-CM code if an exact match is available. Under government and most other payor

本书版权归John Wiley & Sons Inc.所有

programs, a narrative or ICD-CM diagnosis is absolutely required on all claims submitted, and laboratories must make a serious attempt to obtain this information if it is not provided. The transition from version 10 (ICD-10-CM) to version 11 (ICD-11-CM) is anticipated in the near future and will require laboratory review and implementation.

The Requisition

The requisition, whether online or manual, represents the major tool used by ordering providers to select tests for use in patient management. Thus, it should be designed to be user friendly and include all data elements required for billing. All orderable tests must be clearly defined and represent only AMA-developed and CMS-approved codes representing procedures, individual tests, or panels. If a special situation exists (as described below), this too should be indicated on the requisition. It is not required that the actual CPT code be on the requisition, although many billing experts recommend that it should be. If not on the requisition, CPT codes must be readily accessible elsewhere (e.g., in the service manual). In the event of receipt of an ambiguous order, the laboratory is required to take action to clarify the order. An ambiguous order is one that does not match the test description or conditions in the laboratory. In these cases, a laboratory should not attempt to guess the ordering provider's intent. Rather, it is necessary to contact the physician to determine the exact procedure desired.

Special Ordering Situations

There are several situations in which an orderable procedure may be represented by more than one code, and these must be clearly indicated on a requisition (Table 35.3). First is a reflex procedure. A reflex test is defined as a second related codeable test that is performed automatically when initial tests are positive or abnormal. Replicate testing performed per protocol and repeat testing performed to confirm or verify a result are not considered a reflex (17).

Second is a composite procedure. This term is most commonly used to describe the battery of tests that are included under end-stage renal disease (ESRD) payment, but the term can also be used to describe the routine simultaneous use of two or more unique codes to meet accreditory guidelines or in accordance with an accepted standard of practice (e.g., microbiology: test 1, microbial stain; test 2, microbial culture; test 3, isolate identification; test 4, antimicrobial susceptibility testing). Another term, "code-stacking," has been used in particular reference to procedural step code groups previously used in molecular pathology but this approach was replaced with an analyte-specific coding approach in 2013 that has been significantly expanded over time.

Table 35.3 Examples of reflex test procedures[a]

Laboratory category	Primary test	Reflex test
Immunology	RPR or VDRL, positive	Specific treponemal serology and RPR titer
Microbiology	Primary culture, positive	Identification and susceptibility
Molecular diagnostics	Pap smear with ASCUS	HPV DNA
Toxicology	Qualitative drug screen, positive	Drug confirmation, each procedure
Urinalysis	Nonculture bacteriuria screen or biochemical urinalysis	Urine culture positive
Chemistry (7)	Quantitative RT-PCR for HCV	If quantitative test result is below limit of detection, qualitative RT-PCR for HCV is performed
Hematology (14)	Reticulocyte count, erythrocyte morphology, bilirubin, haptoglobin (help diagnose hemolytic anemias)	If acute intravascular hemolysis is suspected, plasma and urinary hemoglobins and a DAT may be ordered

[a] RPR, rapid plasma reagin; VDRL, Venereal Disease Research Laboratory; HPV, human papillomavirus; RT-PCR, reverse transcriptase PCR; HCV, hepatitis C virus; DAT, direct anti-human globulin test.

Under compliance guidance, the codes used for both reflex and composite coding situations should meet medical-necessity requirements. In addition, what is actually done and its associated codes must be clearly communicated to the ordering provider, generally through the requisition and service manual. There should also be documentation of such communication, and notifications should be performed annually. For outpatient providers a written annual notice should be sent, but for inpatient care annual approval by the medical staff may be preferred. Finally, each ordering provider must have the clear choice to not have the testing performed in that manner, but rather to order only specific codes if desired.

The third multiple-code situation is the "custom panel." This is a grouping of several independent codes made available as a single orderable procedure, usually as an ordering convenience, and generally specifically requested by a physician to meet his or her own style of practice. These kinds of test order groupings must meet the same medical-necessity determination requirements as the individual components and require that a physician formally acknowledge in writing his or her understanding of such on an annual basis.

Last, one should address the issue of "standing orders." This practice is most common for chronically ill individuals with extended courses of treatment, as in a skilled-

本书版权归John Wiley & Sons Inc.所有

nursing facility or ESRD setting. Although not prohibited, the practice is discouraged. The reason is that the tests included in the order must meet medical-necessity requirements for the date of service, and that information may not be known in advance. At a minimum, laboratories should ensure that standing orders have a fixed term, generally no more than a year and preferably a shorter interval and be clearly defined in writing and acknowledged formally by the ordering provider.

Medical-Necessity Issues

"Medical necessity" has a specific meaning for the CMS but is a concept used by other payors as well. It is a determination by the payor of whether the ordering provider's reason for ordering a test represents a condition that meets criteria for coverage and reimbursement at a designated level. The term does not address whether a particular test is believed to be necessary for management of an individual patient by a physician. From the CPT and ICD-CM codes, the laboratory should be able to make a determination of whether a claim will be paid for by a third-party payor based on its knowledge of the particular billing rules of the payor. The complexity of the rules, and the numbers of payors that any given laboratory may do business with, is such that electronic rule-based claim review is essential to accomplish this task. If it is determined that payment is unlikely, then the laboratory should obtain a waiver of financial liability from the patient (e.g., the Medicare ABN) (18). In the common setting of specimen collection by the ordering provider, the ordering provider should make this determination and obtain the waiver. It is acceptable for laboratories to make copies of LCDs and NCDs, as well as NCCI edits, including in the form of a software application, available to ordering providers to facilitate this process. It is also recommended that laboratories clearly indicate on requisition tests that are likely to be noncovered or have limited coverage (i.e., LCDs and NCDs). For Medicare, an annual notice should be sent to physicians describing laboratory practices with respect to coding and billing and reaffirming the concept of medical necessity in making a payment determination. Indeed, it is the responsibility of the laboratory to ensure that physicians are aware of all Medicare and other payor rules for coverage.

Record Retention

Adequate record retention is an extremely important component of a compliance program. All records should be maintained as required by applicable federal statutes and regulations for use if needed in the investigation of potential fraud or abuse. There might also be additional requirements based on voluntary accreditation standards and state laws and regulations. Federal statutory retention times include the following:

- *42 CFR 482.24(b)((1))*. Condition of participation for hospitals in federal programs specifies 5 years.
- *42 CFR 488.5(a)*. Discussion of accreditation standards deemed to meet Medicare conditions of participation indicates variable times of at least 5 years.
- *42 CFR 493.1105*. CLIA of 1988 (CLIA '88) specifies 2 years for test requisitions.
- *42 CFR493.1107*. CLIA '88 specifies 2 years for testing records.
- *42 CFR 493.1107 and 1109*. CLIA '88 specifies that transfusion medicine records should be held for a minimum of 5 years.
- *42 CFR 493.1257(g)*. CLIA '88 specifies that cytology slides should be held for 5 years.
- *42 CFR 1003.132*. The False Claims Act specifies that claims related to civil actions may be initiated up to 6 years after the date of claim presentation.

While most laboratorians are aware of the CLIA requirements, the need to maintain records that document test orders and test performance for a longer period in case civil or criminal legal action is taken is not as well appreciated.

Marketing Practices

All marketing efforts in a laboratory setting should adhere to strict principles of offering clear, correct, nondeceptive, and fully informative guidance and pricing regarding testing services. It is simply good laboratory medicine practice to ensure that all parties understand both the testing and billing processes.

Pricing and Inducements

No free supplies, equipment, or services of any kind should be offered that are not an essential component of performing and reporting laboratory tests. No other services or items should be provided that may be construed as an inducement for the submission of federally reimbursed work. Rather, any special services (e.g., additional office work, laboratory work unrelated to the contracted services, provision of data summaries) should be billed to a client at a fair market value rate. Similarly, prices charged to physicians and other payors should represent fair market value and be based on careful and consistent cost accounting practices for each test procedure. For Medicare in particular, you cannot establish a charge to be substantially in excess of any charge offered to another payor. "Substantially in excess" has been generally defined as 120% of the average charge to all payors for each test. Although you will likely not be reimbursed at your charge rate, the data may be used in the determination of

本书版权归John Wiley & Sons Inc.所有

the NLA if required under PAMA. Discounts that place charges below costs, particularly if offered to match competitor pricing, may be viewed as an inducement. In addition, failure to attempt to bill patients for services that were denied on the basis of medical necessity may also be viewed as an inducement. Any form of inducement is a violation of both the Stark Law and Anti-Kickback Statutes and may therefore be a federal offense.

Ordering Provider and Patient Communication

To ensure that all parties understand the testing and billing processes, it is critical that a laboratory establish clear and consistent lines of communication. For ordering providers, coding information should be readily accessible through a service manual or other test-listing document. The laboratory must send an annual notice to each client detailing the ordering and billing processes and must clearly document any special ordering or billing situations. In particular, the notice should address current NCDs and LCDs, use of AMA-developed and custom panels, special situations involving reflex and composite testing or standing orders, appropriate use of an ABN, and current fee schedule information. Finally, the name of the individual who serves as the CLIA clinical consultant for a specific laboratory should be readily available. In a healthcare institution or system setting, it may be most convenient to provide annual notice at a medical staff meeting.

Open lines of communication between providers and payors regarding billing must be maintained during regular business hours. For patients, open lines of communication regarding billing must similarly be available. It may be helpful to have written patient information readily available that describes unfamiliar terms such as medical necessity and ABN. As in all endeavors, a thorough, consistent, and honest approach is the best course of action.

Fraud Alerts and Advisory Opinions

A number of guidance documents are issued on a regular basis by both the CMS and the OIG. Each laboratory CCO and CC should be aware of the issuance of any such documents. Obviously, laboratories should remain abreast of any new coverage decisions and edits that are issued by any payor. Other documents that should be reviewed include relevant program transmittals from the CMS, specific fraud alerts from the OIG, and advisory opinions issued by the OIG that are specific to a given provider situation but may set important precedents. Also important is the annual OIG Work Plan (10) that describes proposals designed to reduce reimbursement for services that have been assessed to be at risk for overpayment as well as the related OIG Top Unimplemented Recommendations to promote program integrity (11). Every work plan since the issuance of the Compliance Program Guidance in 1998 has included clinical laboratory targets. One other source of information on emerging issues is the HHS Advisory Opinion (19). Careful review of these documents will prepare a laboratory to effectively manage situations with emerging compliance ramifications.

Auditing and Monitoring

To demonstrate that a compliance program is effective, it is essential to have in place a series of monitors and audits (20). Monitors simply measure a parameter that can be used to assess some aspect of compliance. The most common monitor is test utilization. The OIG recommends an annual review of the top 30 test codes ordered to determine if any significant pattern changes (i.e., greater than 10%) are noted. Further investigation should be performed to ascertain the reasons for the change. In most cases, the change can easily be explained by test volume growth, new-procedure implementation, or correct-coding adjustments. However, if not explainable, additional review of the reasons for testing may be indicated. Another essential monitor is the tracking of denied claims (21). Patterns that are identified are important indicators of possible billing problems that may be rectified by some specific process adjustment.

Audits are a more comprehensive and systematic review of a specific compliance policy to determine that the policy is in fact being followed. For each compliance policy in place (Table 35.1), there should be some measurable parameter that assesses its effectiveness. The most common audit is one that simply reviews a statistically significant sampling of claims to determine the tests that were ordered, confirm that they were performed, and the results were reported, and confirm that the tests were billed correctly. This audit technique encompasses the entire process. Other audits may be applicable to a specific policy. For example, one might review the accuracy of translation of narrative diagnoses to ICD-CM codes, the frequency and appropriateness of obtaining ABNs, and whether a high percentage of supplies for sample collection are being returned with samples and requested services. The overall effectiveness of the training program might be assessed by examination of employees after training, and the effectiveness of the overall program might be determined by an employee survey. Careful and complete audits are a time-consuming task and are often outsourced to external parties. This is an acceptable practice, although review of findings and plans for improvement remain the responsibility of the CCO and the CC.

Response to Possible Fraud or Abuse

Every laboratory must have plans in place to evaluate complaints that indicate the possibility of fraud or abuse. If a complaint is determined to actually indicate receipt

本书版权归John Wiley & Sons Inc.所有

of improper payment, the OIG Compliance Program clearly specifies the actions that must be taken. If the overpayment represents a true mistake, caused by misunderstanding or misapplication of rules, the laboratory should take prompt action to correct the problem and to make voluntary repayment as outlined in the OIG Compliance Program. Evidence of systematic "rule-bending" (abuse) can be handled in a similar manner. If a specific employee is found to be responsible, standard disciplinary actions should be taken. If, however, there is evidence of intent to defraud a payor, the potential violation should be reported to the DOJ. All subsequent actions will then be directed as part of a legal investigation process, with outcomes including both settlements and indictments. For individuals, laboratories should maintain a zero-tolerance policy toward deliberate disregard for compliance policies. In the event of an indictment, both facilities and individuals will be listed on the OIG sanction list and prohibited from doing further business with or for the federal government. Other nonfederal payors may similarly file suits, and they may also exclude an entity from participation when evidence of a systematic error representing fraud or abuse is found.

Laboratories must also be prepared to deal with a legal process emanating from an external complaint reported by a whistle-blower directly to the Department of Justice. There should be a well-defined plan of action in which employees are advised as to the correct course, particularly with regard to notification of superiors. Certainly, cooperation is expected, and any type of obstruction is to be avoided. However, laboratories should take steps to legally protect their interests. For example, categories of documents protected by client-attorney privileges should be clearly marked as such and maintained separately, and legal counsel should be sought as soon as possible after recognition or allegation of fraud or abuse.

Laboratory Examples of Fraud and Abuse

Sadly, there are many examples of deliberate attempts by a small number of healthcare providers to obtain improper and illegal reimbursement for services that have been described by the OIG (22–25). Genetic tests in particular have been the subject of intense scrutiny recently (26, 27). While some investigations have resulted in indictments, many more are settled out of court when it is recognized that there may be actions that could be construed as evidence of impropriety. Some of the more visible laboratory compliance cases have involved the following practices:

- Billing for tests not performed, e.g., billing for identifications and susceptibilities on "no growth" urine samples
- Failure to clearly define the test being performed, e.g., performing a complete blood count (CBC) with differential but describing the test as CBC only
- Routinely performing additional tests that were not part of the original order, e.g., adding a chemistry test to an approved panel or, more recently, adding tests as a component of COVID-19 testing, including respiratory pathogen panels, allergy tests, and genetic tests
- Improper billing for panels, e.g., billing for a chemistry panel when not all components of the panel were performed
- Routinely performing reflex testing that was not subject to a defined review process, e.g., performing microscopic analysis or a bacterial culture on a urine sample with abnormal urinalysis
- Routinely reporting results for and billing tests when quality control was out of range and therefore in violation of CLIA
- Routinely performing procedures, including laboratory testing, in specific DRGs to artificially inflate the payment, e.g., in the case of pneumonia

Unfortunately, these isolated episodes of improper billing influence the overall view that many who hold political office share, i.e., (i) that laboratories cannot be trusted and must be subjected to close scrutiny and (ii) that overpayment is rampant, and therefore payment reductions are justified. To combat these negative opinions, it is paramount that laboratorians adopt the attitude that a successful compliance program that guarantees that laboratories "get paid right" is essential to survival.

SUMMARY

Compliance has assumed a new meaning in the last several decades as laboratories have been accused of and found guilty of fraud and abuse. The actual concept of adherence to rules and regulations is not new, however. Laboratories must comply with the rules and regulations promulgated by many government entities. What is new is the concept that laboratorians must also comply with rules and regulations pertaining to reimbursement. A sound knowledge of coding and billing practices is an absolute key to success. The OIG Compliance Program Guidance for Clinical Laboratories published in 1998 continues to provide the basis for development of policies and procedures that ensure that laboratories are paid appropriately for what they do. In essence, the document provides the basis for application of commonsense principles for receiving requests for laboratory services, performing those services, and getting paid for those

本书版权归John Wiley & Sons Inc.所有

services. While the OIG Compliance Guidance is considered voluntary, provisions in the PPACA specify that compliance programs should be considered mandatory. Indeed, the importance of an effective reimbursement compliance program should be considered as vital to the success of a clinical laboratory as is compliance with CLIA regulations.

KEY POINTS

- Compliance has taken on a new meaning during the last few years as laboratories have been accused of and found guilty of fraud and abuse.
- Laboratories and laboratorians must be knowledgeable about and comply with rules and regulations related to reimbursement.
- It is mandatory that laboratory personnel maintain a thorough understanding of coding and billing practices.
- All laboratories should have in place a comprehensive compliance program, with its key provisions and requirements in effect at all times with a zero-tolerance approach.
- It is critical and appropriate that laboratories be paid for the services they provide within the framework of the compliance regulations.

GLOSSARY AND APPENDIXES

Reader please note that the Glossary and Appendixes for the three chapters in this section are combined and provided at the end of chapter 34.

REFERENCES

1. **Scott M, Nguyen D**. 2009. Clinical laboratory compliance: something old, something new. *Lab Med* **40**:428–435.

2. **OIG**. 2022. Labs with questionably high billing for additional tests alongside COVID-19 tests warrant further scrutiny. OEI-09-20-00510. https://oig.hhs.gov/oei/reports/OEI-09-20-00510.pdf. Accessed 1 March 2023.

3. **OIG**. 2000. Medicare payments for clinical laboratory services. Vulnerabilities and control. OEI-05-00-00070. https://oig.hhs.gov/oei/reports/oei-05-00-00070.pdf. Accessed 1 March 2023.

4. **Jampol ML, Taylor ZS**. 2022. Four years after EKRA: Reminders for clinical laboratories. Health Law Advisor. https://www.healthlawadvisor.com/2022/10/13/four-years-after-ekra-reminders-for-clinical-laboratories/. Accessed 1 March 2023.

5. **GAO**. 2010. Medicare fraud, waste, and abuse: challenges and strategies for preventing improper payments. https://www.gao.gov/products/gao-10-844t. Accessed 1 March 2023.

6. **GAO**. 2014. Medicare fraud: progress made, but more action needed to address medicare fraud, waste, and abuse. https://www.gao.gov/assets/gao-14-560t.pdf. Accessed 1 March 2023.

7. **DOJ**. 2022. Annual Report of the Departments of Health and Human Services and Justice. Health Care Fraud and Abuse Control Program FY 2021. https://oig.hhs.gov/publications/docs/hcfac/FY2021-hcfac.pdf. Accessed 1 March 2023.

8. **Mazer RE**. 2018. Clinical laboratory compliance issues. *J Healthcare Compliance* **20**: Sept–Oct 1–13. https://www.bakerdonelson.com/webfiles/Bios/HCCJMazer.pdf. Accessed 15 October 2023.

9. **Goldman TR**. 2012. Health policy brief: eliminating fraud and abuse. http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_72.pdf. Accessed 1 March 2023.

10. **Office of Inspector General**. 2023. Work plan. https://oig.hhs.gov/reports-and-publications/workplan/index.asp. Accessed 1 March 2023.

11. **Office of Inspector General**. 2022. OIG's top unimplemented recommendations: solutions to reduce fraud, waste, and abuse in HHS programs. https://oig.hhs.gov/documents/top-unimplemented-recommendations/1102/compendium2022.pdf. Accessed 1 March 2023.

12. **Federal Register**. 1998. Publication of OIG Compliance Program Guidance for Clinical Laboratories. *Fed Regist* **63**:45076–45087.

13. **Ahlin PA, Weiss RL**. 2007. Risk management and compliance in pathology and laboratory medicine. *Clin Lab Med* **27**: 859–873, vii.

14. **Hansen K, Lavanty D**. 2004. Enforcement of CLIA and billing regulations. *Clin Lab Sci* **17**:2–3.

15. **Leuno ST, Park JY**. 2020. Laboratory regulations and compliance, p 247–264. *In* Clarke W, Marzinke M (ed), *Contemporary Practice in Clinical Chemistry*, 4th ed. AACC Press, Washington, DC.

16. **Office of Inspector General**. 2014. Questionable billing for Medicare Part B clinical laboratory services. OEI-03-11-00730. https://oig.hhs.gov/oei/reports/oei-03-11-00730.pdf. Accessed 1 March 2023.

17. **MacMillan DH, Soderberg BL, Laposata M**. 2001. Regulations regarding reflexive testing and narrative interpretations in laboratory medicine. *Am J Clin Pathol* **116**(Suppl):S129–S132.

18. **Carter D**. 2003. Obtaining advance beneficiary notices for Medicare physician providers. *J Med Pract Manage* **19**:10–18.

19. **Climo CJ**. 2015. A laboratory of regulation: the untapped potential of the HHS Advisory Opinion power. *Vanderbilt Law Rev* **68**:1761–1794.

20. **Keoppel P**. 2001. Performing laboratory compliance audits. *Clin Leadersh Manag Rev* **15**:368–375.

21. **Mesaros F Jr.** 2000. The remittance advice, auditing for compliance. *Clin Leadersh Manag Rev* **14**:69–71.

22. **OIG**. 2018. Medicare improperly paid providers for specimen validity tests billed in combination with urine drug tests A-09-16-02034. https://oig.hhs.gov/oas/reports/region9/91602034.pdf. Accessed 1 March 2023.

23. **OIG**. 2021. Medicare could have saved up to $20 million over 5 years if CMS oversight had been adequate to prevent payments for medically unnecessary cholesterol blood tests. A-09-19-03027.

本书版权归John Wiley & Sons Inc.所有

https://oig.hhs.gov/oas/reports/region9/91903027.pdf. Accessed 1 March 2023.

24. OIG. 2021. Trends in genetic tests provided under Medicare Part B indicate areas of possible concern. A-09-20-03027. https://oig.hhs.gov/oas/reports/region9/92003027.pdf. Accessed 1 March 2023.

25. OIG. 2022. Medicare Part B spending on lab tests increased in 2021, driven by higher volume of COVID-19 tests, genetic tests, and chemistry tests. OEI-09-22-00400. https://oig.hhs.gov/oei/reports/OEI-09-22-00400.pdf. Accessed 1 March 2023.

26. Hoey LG, **Gardner DK**. 2016. Taming the "wild west": enforcement trends and reimbursement issues facing independent clinical laboratories. *BNA's Health Law Reporter* **25**:HLR 501.

27. Owens AM. 2020. Genetic testing: The new wild west for healthcare fraud. Criminal Justice. https://www.americanbar.org/groups/criminal_justice/publications/criminal-justice-magazine/2020/spring/genetic-testing-new-wild-west-health-care-fraud/. Accessed 1 March 2023.

本书版权归John Wiley & Sons Inc.所有

36

Introduction
Pitfalls in Cost Accounting
Laboratory Profitability
Balance Sheets • Income Statements • Cash Flow Statements
Key Indicators
Key Income Indicators • Key Expense Indicators
Institutional Profitability
Human Profitability
Laboratory Value
SUMMARY
KEY POINTS
GLOSSARY AND APPENDIXES
REFERENCES

Determination of Profitability

Vickie S. Baselski, Alice S. Weissfeld, and Fran Sorrell

OBJECTIVES

To describe those items that are included in the true costs of a laboratory procedure

To discuss possible reasons why cost analyses rarely account for all expenditures

To list the three primary tools used in the laboratory to assess profitability

To describe several of the key indicators used to evaluate an institution's performance (benchmarking)

To discuss the term "outcome assessment" and its relationship to institutional profitability

To discuss the concept of human profitability and its relationship to quality patient care

To describe the trend toward value-based laboratory medicine

> *If you don't do it excellently, don't do it at all. Because if it's not excellent, it won't be profitable or fun, and if you're not in business for fun or profit, what the hell are you doing there?*
>
> Robert Townsend (from *Further Up the Organization*), 1988

In any business, including laboratory medicine, the ultimate goal is to be profitable. From financial profits come funds for enhancements in facilities, equipment, and personnel. From profits also come the means to continue to exist as either a for-profit or nonprofit entity. A laboratory must certainly be profitable as a business unit, and there are well-defined financial monitoring tools to demonstrate this. However, profits in laboratory medicine are measured by more than simply dollars made or lost and dollars spent or saved. A profitable laboratory is also one that contributes positively to patient care. In the current healthcare climate, the term "outcome assessment" has been used to describe the success or failure of a disease management strategy with regard to both financial and medical measures (1). The profitability of an institution arises at least in part from effective and efficient patient care, including the effective and efficient use of laboratory medicine. In fact, provision of healthcare services is undergoing a major shift under healthcare reform. The emphasis is moving from one focused on procedures to one focused on patients. In today's world the laboratory is being viewed as neither a "cash cow" nor a "cost center," but as a unit vital to an institution's ability to provide healthcare services. Therefore, in laboratory management today,

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch36.

本书版权归John Wiley & Sons Inc.所有

one must be able to discuss both the individual profitability of a laboratory unit and the contribution of the laboratory to the profitability of patient care. It must also be appreciated that at least in part, one can also measure the satisfaction of making a positive contribution to patient care as a measure of human profitability. In addition, one must understand that laboratory medicine is a service that provides value, not a simple commodity to be delivered at the lowest cost possible.

Reader please note that the Glossary and Appendixes for the three chapters in this section are combined and provided at the end of chapter 34.

Pitfalls in Cost Accounting

Integral to any determination of profitability is a clear understanding of the true costs of a procedure. Chapter 33 deals with cost accounting as it pertains to reimbursement, but a few key concepts justify consideration here as well (2, 3). First is that a complete cost analysis should consider all identifiable costs for a service. One must consider many factors, including all of the following:

- Direct material costs, including all consumables, quality control, repeats, and wastage
- Direct labor costs, including benefit costs
- Equipment and other capital costs, either leasing or depreciation based on purchase as well as maintenance and repair costs
- Laboratory-specific indirect costs, generally based on an allocation method and including licensure and accreditation maintenance (e.g., inspections, documents, proficiency testing, quality control and improvement) and training or continuing-education costs
- Indirect facility costs, also generally based on allocation of a percentage of costs due to utilities, rent or purchase notes, housekeeping and medical waste disposal, and information technology and communication systems
- Indirect administrative costs, again allocated and including courier services, marketing, customer service, and financial processes (e.g., billing, collections, payments)

Careful systematic consideration of all of these factors will allow a laboratory to make reasonable decisions regarding price structure for fee-for-service testing services. The information is particularly useful when assessing whether a discounted fee schedule approximates the laboratory expenses. However, cost analyses in any business, including in a laboratory, are rarely able to account for anywhere near 100% of expenditures. There are frequently many unpredictable variables, particularly in areas in which the laboratory has little or no control. For example, supplies provided for collection and submission of samples are rarely accounted for 100% on return, and rates of re-collections due to preanalytical issues, repeats due to analytical issues, and wastage due to quality control failures or insufficient product in a kit lot to complete an additional run all contribute to inaccuracies in projecting total technical expenses. In addition, allocated costs are similarly subject to changes associated with unanticipated events.

In a like manner, attempts to account for anticipated revenue are also subject to inherent inaccuracies. The inability to obtain critical documentation, misunderstanding or misapplication of payor rules or issuances of new rules, failure to obtain patient waivers of financial liability, and failure to collect billed amounts due all contribute to a reduction in anticipated revenues.

To determine true costs and revenues, and to subsequently assess profitability as well as efficiency, it is necessary to measure resources actually expended, including through amortization, and compare that measurement to amounts actually collected. In a strict accounting sense, revenues less expenses equals profit, and revenues divided by expenses equals profitability.

Laboratory Profitability

Analyses to assess laboratory profitability are usually performed on a regular basis, not less than quarterly and typically monthly. To accomplish this there are three primary tools used in the laboratory setting: the balance sheet, the income statement, and the cash flow statement (2, 3).

Balance Sheets

The balance sheet provides an indicator of an organization's overall financial well-being. It compares an organization's total assets to its total liabilities. In the laboratory, assets include not only cash holdings and accounts receivable but also facilities and all possessions used to create services (e.g., equipment and supplies). Liabilities include all money owed and, in the case of a for-profit institution, shareholder equity amounts. Simply stated, a balance sheet should at least balance. However, to be considered profitable, total assets should exceed total liabilities. From a laboratory management perspective, while a positive balance sheet is critical to success and may certainly be reassuring to employees and shareholders, it provides little information that may be used to improve operational efficiency in an individual laboratory setting.

Income Statements

An income statement is used to demonstrate profitability over a given period. These statements are also known as "profit and loss" statements because they compare the net profit for a specified period to the total expenses of doing

本书版权归John Wiley & Sons Inc.所有

business during the same period. Calculating total gross income and subtracting total expenses determine net profits or losses. The net profit may also be expressed as a percentage of gross income and may be referred to as the profit margin. The net profit should not be considered an absolute value, however. This figure is generally determined prior to consideration of taxes and interest amounts due and is referred to as earnings before taxes and interest. Clearly, an accurate determination of profit requires considerations of these expenses as well.

Income statements also frequently include figures reflecting budgeted and expected revenue and expense amounts. Thus, they allow a laboratory to assess whether there are significant variances from the amounts expected in both categories. In general, variances of more than 3 to 5% require evaluation to determine if other downstream adjustments may be necessary. For example, loss or gain of a major client or medical specialty service may necessitate renegotiation of standing reagent orders for delivery of a more appropriate quantity of supplies.

As with the balance sheet, the income statement often reflects the overall financial situation of a laboratory and therefore is most useful to upper management for determining profitability for the entire laboratory. However, this statement may be configured to reflect the income and expenses of a specific department as well. In this configuration, individual department heads may find the document useful to assess whether expenses and income are as expected and to assess whether an individual department is profitable.

Cash Flow Statements

Cash flow statements demonstrate exactly what the name implies. They provide a summary of the amounts paid out and to whom (accounts payable) and the amounts received in payment for services or other items and activities (accounts receivable). Again, simply stated, accounts receivable should exceed accounts payable. Similar to balance sheets, these documents are not very useful in assessing operational efficiency for a given laboratory.

Key Indicators

In addition to these institutional summary reports, most laboratories employ the use of key indicators to assess not only profitability but also overall operational efficiency. Such indicators are often financial or other ratios (i.e., a numerator/a denominator) that may be used to evaluate an institution's performance over time or in comparison to that of like institutions. This practice is known as "benchmarking" and can provide very useful information for operational improvement leading to financial benefit (4). Key indicators can assess both sides of doing business: income and expenses. In addition, they are useful in both prospective and retrospective payment systems.

Key Income Indicators

Key income indicators are used to determine whether a laboratory is financially successful. They measure both success in an institutional sense and success from an investment perspective. In a business sense, monitors generally compare assets to liabilities or revenue to expenses. Clearly the expectation is that in each case the ratio should exceed 1. In addition, it is customary to track volume indicators that translate into income. Most laboratories track daily numbers of billable tests and look for significant deviations that may have a financial impact. For independent laboratories, new sales or lost business can also be used to monitor potential for future financial success or failure.

From an investment perspective, for-profit laboratories must also demonstrate earning potential for investors. This is usually done by comparing price per share to earnings per share. Here as well, data on volumes may be used to demonstrate earning potential.

It should be appreciated that tracking volumes has potential utility beyond simply predicting income in fee-for-service-payment systems. In a prospective payment system, tracking utilization is an important activity (5, 6). One may detect overutilization of testing outside of what is expected for a given patient population. However, one can also detect underutilization of services deemed to be necessary for patient management. Either situation can contribute to less-than-optimal patient care. Recall as well that utilization tracking is also an important component of compliance activities (chapter 35).

Key Expense Indicators

While income monitors should show favorable performance for a laboratory to be considered profitable, monitors that assess efficiency or effectiveness over time are more useful to individual laboratory managers seeking to ensure that their departments contribute to overall profitability. While it is useful to monitor indirect and fixed expenses for deviation and for comparability to those of similar institutions, of most importance to laboratorians are those monitors that assess an aspect that can be adjusted or controlled. Both labor and material expenses are considered useful for the development of such monitors.

Monitors for labor efficiency generally focus on productivity. It has become customary to use billable tests (i.e., Current Procedural Terminology [CPT] or codable tests) produced per full-time equivalent for this purpose, although the monitor may also be inverted and expressed as time paid or time worked per billable test. There is wide variation in expectations for productivity based on the department being evaluated. Obviously, an automated-testing department will show higher output than a laboratory employing more manual processes. For this reason, productivity assessments are most useful when used for benchmarking either temporally to assess performance of

本书版权归John Wiley & Sons Inc.所有

a single institution over time or when comparing laboratories that have been determined to be comparable in both scope and processes for services provided.

Another commonly used labor effectiveness monitor is percentage of overtime used. In a properly staffed laboratory, overtime usage should be minimal. Excessive overtime payments, generally paid at an elevated hourly rate, reduce profitability.

Expense monitors generally focus on actual costs per billable test. These monitors may be constructed to be comprehensive and include all direct costs (materials and labor) as well as an allocated indirect cost. For benchmarking purposes and for assessing new methods for the laboratory, a comprehensive cost-per-reportable monitor is generally preferred. However, material costs as a stand-alone item should also be evaluated. A monitor of material cost per billable test is, as for labor cost per billable test, most useful for temporal evaluations or in comparison to that of a similar laboratory. These kinds of analyses are distinct from an actual cost analysis for a specific billable test in that they measure the actual and not simply the expected cost. A wide variation between calculated cost and actual cost per billable test is cause for concern regarding possible inefficiencies.

One additional monitor for material use efficiency is actual versus potential utilization rates for specific high-cost items. With all commercial kit products, it is common for wastage to occur when small amounts of product remain that are insufficient for a complete run including controls and patient samples. Utilization rates of substantially less than 100% may indicate a need to redesign workflow processes to improve efficiency.

Institutional Profitability

It is clear that each individual laboratory must be able to operate efficiently within a defined budget and that each laboratory manager must continue to seek ways to operate more effectively to decrease overall costs in an era of ever-continuing decreases in available revenues. However, laboratory medicine is unique in that the product, which has defined costs and specific individual value, may also have a positive financial impact in a manner not directly financially benefiting the laboratory. In other words, the results of a specific test may be used to improve the clinical outcome for a patient such that the total costs of providing care for that patient are decreased. Thus, the beneficiary of the savings is the payor and not the laboratory providing essential information. Therefore, laboratory managers and payors must not be shortsighted in making a decision to perform and pay for a particular test based simply on the laboratory economics of the situation. The term "outcome assessment" has been used to describe the process of determining whether a particular measure will have a positive clinical and presumably financial impact on patient care.

In laboratory medicine, there are several well-designed studies that demonstrate healthcare system savings emanating from the performance of a particular laboratory procedure (7). Rapid diagnostic procedures may allow for more timely institution of therapeutic and infection prevention protocols that may contribute to overall lower healthcare costs. For example, implementation of rapid antimicrobial susceptibility testing via an automated system was shown to decrease length of stay, use of additional services and drugs, and overall hospital charges compared to an overnight system (8). In a nursing home setting, implementation of rapid influenza virus antigen testing was shown to decrease the numbers of secondary cases through prompt implementation of appropriate prophylaxis, thereby reducing the total costs of caring for ill residents (9), and to improve overall patient management in the emergency department (10). In addition, newer respiratory virus panels may contribute positively to antibiotic stewardship and infection prevention efforts (11). More recently, an evidence-based analysis of rapid blood culture identification methods, often employing molecular methods, has a significantly positive impact on many patient outcome monitors (12). Significant interest is emerging in demonstrating the value of genetic testing in improving patient outcomes (13, 14).

Screening tests used to detect asymptomatic patients or to identify patients at risk for a disease or disease complications may also have an overall positive impact, both on individual patients and on costs of care for populations. In an outpatient setting, testing for *Neisseria gonorrhoeae* has long been known to reduce occurrence of pelvic inflammatory diseases (15) and testing for *Chlamydia trachomatis* using a rapid method was similarly shown to reduce the occurrence of costly secondary salpingitis cases and allowed immediate treatment in a patient population at risk for such due to failure to present for follow-up care (16). In fact, acceptance of routine testing for asymptomatic infections with *Chlamydia* in at-risk patient populations to prevent costly sequelae is recognized in both CDC and United States Preventive Services Task Force (USPSTF) guidelines and has achieved status as a Healthcare Effectiveness Data and Information Set (HEDIS) monitor for effectiveness of healthcare under various payor plans. Similarly, screening for other clinically silent risk factors (e.g., heart disease risk markers), precursor conditions (e.g., human papilloma virus [HPV] testing to predict risk for cervical cancer or a variety of newer molecular pathology tests to identify genetic risk factors for disease), or early evidence of chronic disease conditions (e.g., use of hemoglobin A1c to identify early diabetes) has been shown to reduce overall healthcare costs (7).

In the future, decisions regarding whether to implement costly new technologies in a laboratory will have to take into consideration the financial impact on healthcare in a

本书版权归John Wiley & Sons Inc.所有

more comprehensive sense as well as the immediate financial impact on a given laboratory (17, 18). The suggestion that a "5 R paradigm" to provide "the right test, with the right timing, to the right patient, at the right cost, and for the right clinical reason" is closely aligned with the goal of the Centers for Medicare and Medicaid Services (CMS) to "pay it right" should guide many decisions regarding laboratory testing and its role in patient management (19).

Human Profitability

Through all discussions of profitability, one must not lose sight of the reason for the existence of laboratory medicine as an accepted discipline. The role of the laboratory is to provide data used for effective management of patients. In doing so, laboratory professionals feel a sense of pride and accomplishment in assisting in patient care that cannot easily be measured in financial terms. However, a life saved or salvaged from a serious illness does have a lifetime earning value, which can be calculated, and additional value in terms of human existence that cannot be calculated. The hope is that the human profit margin will be given consideration equal to the financial profit margins in the provision of quality laboratory medicine services. Further, it is fervently hoped that some degree of rationale and logic will be applied in the realm of reimbursement for laboratory services, including in setting appropriate compensation for laboratory scientists performing the work, such that the ultimate financial and human benefit may be reaped (20, 21).

Laboratory Value

While financial profit is essential to the survival of any business, assuming that financial profit alone will ensure that a laboratory is successful is unrealistic in today's economic climate. Table 36.1 outlines some of the essential differences between traditional fee-for-service laboratory medicine and a coordinated care system in which the laboratory is viewed as a component of the care process. In the traditional model, procedures ordered by physicians are the focus, and profitability is determined by evaluating primarily financial data. Increased utilization is encouraged, and the goal is to make money.

With the current focus on healthcare reform, there is a shift in focus from procedures to patients and eventually to population health (22). Testing is used as an integral part of a management strategy, and test groupings are designed to facilitate best practices for the most efficient and effective patient care in a given diagnostic setting. Benefits are measured in terms of improved outcome with regard to quality of care, patient safety, and service. Such benefits may be patient-specific, but cumulative benefits in a population are also important. In fact, CMS is evaluating a number of value-based Bundled Payments of Care Initiatives, and in Maryland, a capitated value-based global payment system has become the primary mechanism for reimbursement from government payors (23). Since payment is increasingly becoming prospective, the goal is to use resources wisely. In essence, profitability results from saving money while also improving patient outcomes.

Healthcare spending cannot continue to grow unchecked, and resources to provide healthcare are not unlimited. Carefully designed studies to assess best practices for overall patient management are essential. Comparative effectiveness studies are needed to determine whether newer, more costly technologies offer any true benefits in terms of patient outcome (24). This particularly applies to newer molecular procedures. Questions about the value of multiplex assays versus targeted assays for infectious diseases, or molecular screening for early cancer diagnosis versus less costly nonmolecular alternatives, and many other questions about the utility of higher-cost molecular assays will continue to be addressed. Laboratory professionals need to be careful stewards of the laboratory component of healthcare expenditures. The value of laboratory medicine and the positive contribution of the data to patient care must be recognized and promoted. In fact, quality ratings are an important aspect of assessing healthcare effectiveness (25), and metrics for assessing quality are often based on laboratory data. Metrics used in both outpatient settings, e.g., HEDIS, and in inpatient settings, e.g., National Healthcare Safety Network (NHSN) hospital-acquired conditions (HACs), provide

Table 36.1 Comparison of features of traditional laboratory medicine and coordinated laboratory medicine

	Traditional laboratory medicine	Coordinated laboratory medicine
Reimbursement	Fee for individual service	Payment for continuum of care
Focus	Procedures	Patients
Approach	Offer individual tests, approved panels, and other well-defined and compliant test groups for physician order	Design test groupings (e.g., checklists, order sets, or care maps/care paths) to facilitate or require best practices for specific diagnostic settings
Performance measures	Focused targets, e.g., financial and productivity ratios	Improved patient or population outcome, e.g., quality, safety, service
Financial goal	Make money	Save money
Measure for profitability	Reimbursement should exceed total expenses	Expenses should improve measurable outcome

本书版权归John Wiley & Sons Inc.所有

good examples of the inclusion of laboratory testing in overall assessment of quality (Table 36.2). Note that CMS has also created a National Quality Strategy to ensure that all persons receive equitable, high-quality, and value-based care that will be based on electronic digital access to core quality measures from the Core Quality Measures Consortium (CQMC). These measures also include clinical laboratory components.

Table 36.2 Examples of quality measures of rates with a laboratory medicine component

Quality monitor	Metric	Laboratory data used
HEDIS: Effectiveness of care[a]	Lead screening in children	Testing for lead blood levels
	Cervical cancer screening	Cytology and high-risk HPV testing
	Colorectal cancer screening	Fecal occult blood test
	Chlamydia screening in women	Chlamydia test
	Appropriate testing for pharyngitis	Group A *Streptococcus* test
	Comprehensive diabetes care	Hemoglobin A1c test
	Inappropriate cervical screening adolescents	Cytology and high-risk HPV testing
	Inappropriate PSA testing in older men	PSA test
NHSN: Healthcare associated infections[b]	Central-line associated bloodstream infections	Blood cultures
	Ventilator associated and non-ventilator associated pneumonia	Lower respiratory tract cultures
	Catheter associated urinary tract infections	Urine cultures
	Surgical site infections	Surgical wound site cultures
	Multiple-drug-resistant organisms	Antibiotic resistance testing
	Clostridioides difficile infection	*Clostridioides difficile* testing
CQMC[c]: Core quality measures	HIV and hepatitis C	HIV, HCV, and syphilis tests
	Comprehensive diabetes care	Hemoglobin A1c
	Cervical cancer screening	Cytology and high-risk HPV testing
	Chlamydia screening	Chlamydia test

[a] HEDIS measures: https://www.ncqa.org/hedis/measures/.
[b] NHSN manual (2023): https://www.cdc.gov/nhsn/pdfs/pscmanual/pcsmanual_current.pdf.
[c] CQMC core measures: https://www.qualityforum.org/CQMC_Core_Sets.aspx.

SUMMARY

Absolute profitability or lack thereof in laboratory medicine may be easily measured within an individual laboratory or laboratory department. To do so, one may use a number of standard accounting tools to compare real expenses to real revenues. However, profitability in laboratory medicine may also extend beyond the boundaries of the laboratory by allowing clinical decisions to be made that have an overall positive impact on a patient's clinical outcome, which may also be measured in financial terms. In addition, a positive clinical outcome may result in many unquantifiable benefits to patients, their families, and their healthcare providers. Therefore, while laboratory professionals must necessarily make sound financial decisions, which allow their facilities to operate with a reasonable budget, administrators and other purchasers of laboratory services must remain cognizant of the overall importance of laboratory medicine to profitability in the provision of healthcare services.

KEY POINTS

- A complete cost analysis must include all identifiable costs for a service.
- Although cost analyses rarely account for all expenditures, it is important to understand what some of these unpredictable variables may be.
- Analyses to assess laboratory profitability usually include balance sheets, income statements, and cash flow statements.
- Key income and expense indicators are required to assess not only profitability but also overall operational efficiency.
- Future decisions regarding implementation of expensive technologies will have to take into consideration the financial impact on healthcare in a more comprehensive sense.

GLOSSARY AND APPENDIXES

Reader please note that the Glossary and Appendixes for the three chapters in this section are combined and provided at the end of chapter 34.

REFERENCES

1. **Wilkinson DS**. 2000. Technology assessment: measuring the outcomes of laboratory practice. *Clin Leadersh Manag Rev* **14**:267–271.

2. **Wilkinson I**. 1999. *Money! Money! Money! A Hitchhiker's Guide to Laboratory Finance*. AACC Press, Washington, DC.

3. **NCCLS**. 1998. *Basic Cost Accounting for Clinical Services. Approved guideline GP11-A*. NCCLS, Wayne, PA.

4. **Wilkinson DS, Reynolds DD**. 2003. Using benchmarking to manage your laboratory. *Clin Leadersh Manag Rev* **17**:5–8.

本书版权归John Wiley & Sons Inc.所有

5. **Hanson C, Plumhoff E**. 2012. Test utilization and the clinical laboratory. *Mayo Med Lab Commun* **37**:1–4.

6. **Kim JY, Dzik WH, Dighe AS, Lewandrowski KB**. 2011. Utilization management in a large urban academic medical center: a 10-year experience. *Am J Clin Pathol* **135**:108–118.

7. **The Lewin Group**. 2005. The value of diagnostics innovation, adoption, and diffusion into healthcare. https://www.lewin.com/content/dam/Lewin/Resources/Site_Sections/Publications/ValueofDiagnostics.pdf. Accessed 1 March 2023.

8. **Doern GV, Vautour R, Gaudet M, Levy B**. 1994. Clinical impact of rapid in vitro susceptibility testing and bacterial identification. *J Clin Microbiol* **32**:1757–1762.

9. **Church DL, Davies HD, Mitton C, Semeniuk H, Logue M, Maxwell C, Donaldson C**. 2002. Clinical and economic evaluation of rapid influenza A virus testing in nursing homes in Calgary, Canada. *Clin Infect Dis* **34**:790–795.

10. **Blaschke AJ, Shapiro DJ, Pavia AT, Byington CL, Ampofo K, Stockmann C, Hersh AL**. 2014. A national study of the impact of rapid influenza testing on clinical care in the emergency department. *J Pediatric Infect Dis Soc* **3**:112–118.

11. **Wils J, Saegeman V, Schuermans A**. 2022. Impact of multiplexed respiratory viral panels on infection control measures and antimicrobial stewardship: a review of the literature. *Eur J Clin Microbiol Infect Dis* **41**:187–202.

12. **Buehler SS, Madison B, Snyder SR, Derzon JH, Cornish NE, Saubolle MA, Weissfeld AS, Weinstein MP, Liebow EB, Wolk DM**. 2016. Effectiveness of practices to increase timeliness of providing targeted therapy for inpatients with bloodstream infections: a laboratory medicine best practices systematic review and meta-analysis. *Clin Microbiol Rev* **29**:59–103.

13. **Mitropoulou C, Litinski V, Kabakchiev B, Rogers S, Patrinos GP**. 2020. PARC report: health outcomes and value of personalized medicine interventions: impact on patient care. *Pharmacogenomics* **21**:797–807.

14. **Ramsey SD, Veenstra DL, Garrison LP Jr, Carlson R, Billings P, Carlson J, Sullivan SD**. 2006. Toward evidence-based assessment for coverage and reimbursement of laboratory-based diagnostic and genetic tests. *Am J Manag Care* **12**:197–202.

15. **Rendtorff RC, Packer H, Glassco S, Levy J**. 1977. The impact of urban community hospital surveillance for gonorrhoea on the infection rate and complications in the female. A progress report. *Br J Vener Dis* **53**:364–367.

16. **Gift TL, Pate MS, Hook EW III, Kassler WJ**. 1999. The rapid test paradox: when fewer cases detected lead to more cases treated: a decision analysis of tests for *Chlamydia trachomatis*. *Sex Transm Dis* **26**:232–240.

17. **Pennestrì F, Banfi G**. 2019. Value-based healthcare: the role of laboratory medicine. *Clin Chem Lab Med* **57**:798–801.

18. **Plebani M, Laposata M, Lippi G**. 2019. Driving the route of laboratory medicine: a manifesto for the future. *Intern Emerg Med* **14**:337–340.

19. **Lippi G, Plebani M**. 2019. Cost, profitability and value of laboratory diagnostics: in God we trust, all others bring data. *J Lab Med* **43**:1–3.

20. **Forsman RW**. 2002. The value of the laboratory professional in the continuum of care. *Clin Leadersh Manag Rev* **16**:370–373.

21. **Beastall GH**. 2013. Adding value to laboratory medicine: a professional responsibility. *Clin Chem Lab Med* **51**:221–227.

22. **Ducatman BS, Ducatman AM, Crawford JM, Laposata M, Sanfilippo F**. 2020. The value proposition for pathologists: a population health approach. *Acad Pathol* **7**(7):2374289519898857.

23. **Emanuel EJ, Johnson DW, Guido M, Goozner M**. 2022. Meaningful Value-Based Payment Reform, Part 1: Maryland Leads The Way. https://www.healthaffairs.org/do/10.1377/forefront.20220205.211264/. Accessed 1 March 2023.

24. **The Lewin Group**. 2010. Laboratory medicine and comparative effectiveness research. https://www.lewin.com/content/dam/Lewin/Resources/Site_Sections/Publications/4210.pdf. Accessed 1 March 2023.

25. **Billmoria KY, Birkmeyer JD, Burstin H, Dimick JB, Maddox KEM, Dahlke AR, DeLancey JO, Pronovost PJ**. 2019. Rating the raters: an evaluation of publicly reported hospital quality rating systems. NEJM Catalyst. https://catalyst.nejm.org/doi/abs/10.1056/CAT.19.0629. Accessed 1 March 2023.

本书版权归John Wiley & Sons Inc.所有

VIII

Outside Marketing and Expansion

(SECTION EDITOR: **Gary W. Procop**)

37 Hospital-Based Laboratory Outreach
Richard Adams, Daniel Kelly, and Lynne S. Garcia

38 Finance and Decision Making in Outreach
Ziad Peerwani

39 Outreach: Obstacles to Hospital Outreach and Enhancing Customer Satisfaction
Beth H. Deaton

本书版权归John Wiley & Sons Inc.所有

本书版权归John Wiley & Sons Inc.所有

37

Introduction
Considering an Outreach Program
Administrative Interest • Exploring the Market • Strategic Plan • Business Plan • Sales Plan
Commitment from All Relevant Parties
Feasibility Report • Philosophical Understanding • Service and Financial Support
Implementing the Outreach Program
People • Processes • Facilities • Equipment • Supplies
Outreach Indicators
Growing the Outreach Program
Assessment • Client Needs
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENTS
REFERENCES

Hospital-Based Laboratory Outreach

Richard Adams, Daniel Kelly, and Lynne S. Garcia

OBJECTIVES

To determine initial interest and develop a position summary
To perform in-depth market and operational assessments
To develop a business plan
To implement the outreach plans
To assess program progress
To evaluate program growth

Growth is never by mere chance; it is the result of forces working together.
James Cash Penney

A LABORATORY OUTREACH PROGRAM CAN BROADEN the scope of services for any hospital laboratory and meet the outpatient needs of the community if it is well researched prior to implementation (1–10). No longer is the laboratory a mere cost center, with reimbursement being paid in many different formats and models all representing a need for an increased level of quality at a lower cost. Arguably, the laboratory has now emerged as the key ingredient to optimize health outcomes while producing new and more comprehensive clinical, anatomic, and molecular testing services. This expanded type of care delivery, combined with the value created by extending the laboratory to the outreach environment, not only provides additional revenues but creates a referral repository of healthcare providers that will expand the brand and result in increased volume to the hospital and related services of the organization. The structure of each outreach program is as unique as the set of customer needs that it satisfies. The key to success is in-depth planning and administrative support. In this chapter, we provide practical, step-by-step guidance on setting up an outreach program.

Considering an Outreach Program

The implementation of outreach programs can present many opportunities:

- Restructuring and strengthening the role of the hospital laboratory in the community
- Redefining the relationship with various reference laboratories
- Increasing market share

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch37.

本书版权归John Wiley & Sons Inc.所有

- Marketing the laboratory's specialty or niche testing
- Promoting vertical integration with other departments within an organization or system
- Establishing potential mergers and affiliations with other outreach programs
- Providing true STAT testing for outpatients
- Instituting systems to evaluate new revenue opportunities
- Managing quality across a continuum of care

Administrative Interest

No outreach program can be successful without the complete support of the facility's administration, including the associated pathologists. This support must include not only operational funding but also strategy, understanding, and backing. Prior to approaching Administration with the idea of an outreach program, developers need to perform an industry analysis, a situational analysis, and a SWOT (strengths, weaknesses, opportunities, and threats) analysis.

Industry analysis. An industry analysis recognizes unique factors within the industry, outside the direct control of the healthcare institution, that affect the survival of the program.

Barriers to entry. Each industry has its own set of entry requirements that must be met by any organization or program desiring to function within that industry. This is also true for an established organization, such as a healthcare institution, which introduces new services into the industry in its market area.

The medical laboratory industry is highly regulated by the U.S. government. These regulations address such operational areas as personnel requirements, quality control and improvement activities, proficiency testing, methodology validation, etc. The Centers for Medicare and Medicaid Services (CMS), the federal agency that administers the Medicare program as well as the Clinical Laboratory Improvement Amendments (CLIA), and the Food and Drug Administration (FDA), which has oversight of medical devices and licensure of blood banks and blood donor services, are the two main federal regulatory agencies. Many states also have statutes covering laboratory operations and personnel.

In addition to regulations dealing with certification or accreditation, job safety regulations are applied by the Occupational Safety and Health Administration (OSHA), including recent directives dealing with needle safety and transport of hazardous materials. The Equal Employment Opportunity Commission (EEOC) oversees employee recruitment and relations. The landmark Stark legislation, prohibiting certain types of physician self-referrals, and *Medicare Fraud and Abuse Alerts*, released by the Office of Inspector General (OIG) and defining illegal inducements to clients by medical laboratories, have further structured how laboratories do business. Recent Medicare requirements related to Advanced Beneficiary Notices (ABNs), determined by Local Medical Review Policies (LMRPs) and National Coverage Decisions (NCDs), and Medicare Secondary Payor (MSP) questionnaires have had an effect on consumers as well as medical laboratories.

Nongovernmental regulations are also present within the laboratory industry. Outreach programs are subject to inspection by The Joint Commission (TJC) as part of an overall hospital accreditation program. Many laboratories undergo voluntary inspections by the College of American Pathologists (CAP) to meet accreditation requirements through "deemed status." This means that one accrediting agency recognizes another accrediting agency's certification in lieu of its own certification; e.g., CAP has deemed status for TJC.

The advent of managed healthcare plans has added another barrier that many outreach programs must overcome. Many plans that are national or regional in scope have contracted with a single laboratory testing entity to perform all the testing for their insured individuals. The large, national laboratories are in a good position to provide services over a large geographic area. In effect, this capability prevents many local or regional outreach programs from even bidding on a contract due to their geographic limitations. The direct impact of these laboratory changes is summarized in Table 37.1.

The managed-care picture, however, is not totally dark. Successful outreach programs have discovered several segments of opportunity that meet changing patient needs, including test utilization, collaboration with other hospitals, enhanced service, implementation of wellness programs, expanded relationships with community healthcare providers, and implementation of laboratory services.

Opportunities for cost management or reductions are readily available through alterations to the staff mix, levels in the organizational structure, and relationships within

Table 37.1 Direct impact of laboratory changes in the current healthcare environment

From:	To:
Revenue center	Cost center
Test-based payment	Capitated payment
Limited utilization controls	Strong utilization controls
High quality	Commodity pricing
Centralized testing	Point-of-care and satellite testing
Internal laboratory	Core laboratory
Semiautomated processing	Fully automated processing
Reputation facilitates referrals	Value-added facilitates referrals

本书版权归John Wiley & Sons Inc.所有

the organization. Cost analysis becomes a necessity. Supply and equipment costs may be examined. Make-versus-buy decisions are made. Process improvement and work redesign are examined. All strategies must be framed within the CMS's new payment-for-value program.

To offer a new service or open a new site, the most recent technology must be available to gain a competitive edge. This technology refers not only to laboratory testing equipment but also to the implementation of highly sophisticated information systems including local area network (LAN) and internet-based systems.

Another factor deals with the availability of qualified personnel. Not only is it difficult to recruit personnel, but once they are hired, their learning curve for each laboratory takes weeks, sometimes months. There is very little transfer of process knowledge from facility to facility.

Determinants of supplier power. A few vendors dominate the supplier distribution, including the emerging molecular and genetic testing market. This climate may result in the inability to solve ongoing problems with reliable shipments and repair services from vendors. However, the advent of regional and national group purchasing organizations, such as the Voluntary Hospitals of America, plus the added emphasis on cost-effectiveness, has contributed to the increased number of laboratories that have aggressively negotiated more favorable purchasing agreements.

Determinants of substitution threat. Medical laboratories have seen their activity base within the industry erode. In the past, medical laboratories were the only places where consumers/patients could have laboratory testing done. These laboratories were in the physician office, in the core hospital laboratory, or associated with a reference laboratory. Home testing and laboratory testing at the patient's bedside, rather than in a designated place called "the laboratory," are now available, and utilization is growing at a geometric rate. Many physician office laboratories, emergency rooms, or outreach satellite laboratories are now performing analyses that formerly were done only by hospital laboratories.

Determinants of buyer power. The medical laboratory industry shares a unique characteristic with the rest of the healthcare industry: the ultimate consumer, the patient, is usually not the final purchaser or payor. The term payor or buyer may refer to one of many groups, including patients, individual physicians or physician group practices, employers, federal and state governments through Medicare and Medicaid, insurance companies, and business coalitions.

The components of buyer power are varied. Buyers are powerful if they purchase large volumes of products or services relative to the total provider's volume. Laboratory testing is ordered by physicians and/or physician extenders, although there is a growing national trend toward self-ordering of tests by patients. The major buyers/payors have begun directing the flow through the gatekeepers with direct provider contracting—the use of preferred-provider organizations, managed-care programs that can include capitation or "at-risk" arrangements, or possibly competitive bidding as considered by Medicare. Because most outreach programs are not well differentiated from other outreach programs, it is relatively easy for any payor to switch to another provider.

Price sensitivity. In the past, price has not been a major concern for patients, either because they had insurance coverage or because the costs of laboratory testing were small in proportion to the entire picture. As individual healthcare consumers have become responsible for larger portions of the bill payment, their concern about price has increased. Corporate and government consumers are increasingly concerned about the rising costs of laboratory testing in relation to their total budgets. Consumer demand for lower prices is increasing. Managed-care contracts demand lower prices. Insurance companies have progressed from encouraging their enrollees to use outpatient healthcare services, rather than inpatient, to price shopping among the laboratory providers. Because of the cutbacks in physician reimbursement, physician practices are searching for lower laboratory prices. Although some individuals have raised quality of care as a concern, the overwhelming tide of concern is associated with price.

Rivalry determinants. Many hospital laboratories have entered the outreach industry segment. The character of the industry itself is changing in response to the aging of the population, the diagnosis of newly discovered maladies, and the development of the field of molecular pathology along with genetics and companion diagnostics.

As brand identity or product differentiation continues to expand on the national level, low switching costs, little competitor diversity, and local concentration of outreach providers have increased the rivalry between laboratories. Buyers tend to select outreach programs according to low pricing, quality customer service, rapid test turnaround time, electronic data entry and reporting with medical record interface options, accurate billing methods, and an expanded range of testing available.

Situational analysis. Answering the question "Does an outreach program fit with who we are?" is the purpose of a situational analysis. It describes the major features of the local environment influencing the program's operation. It also describes where the organization is and where it might go. The outreach program must "fit" with the organizational goals.

本书版权归John Wiley & Sons Inc.所有

Background. A background analysis summarizes the organizational factors affecting the potential success of the proposed program. It includes a brief history of the organization or institution including the mission, values, and community needs. A description of the events leading to the laboratory's decision to consider establishing an outreach program is desirable.

Current activity and normal forecast. The background information is followed by a summary of key performance indicators for the past few years and a forecast of future volume under normal conditions. This assumes no major changes in the marketing environment or strategies. The forecast may be done first without considering the proposed outreach volume and then with that projected volume. The comparison of the two forecasts provides important information needed to decide whether the costs outweigh the benefits of establishing an outreach program.

Market description. The primary purpose of a market description is to clarify the market in which the outreach program will be operating. Some of the elements that may be included are a map of the proposed service area, a list of targeted clients or customers, a demographic profile of the service area, a discussion of other competitors, and a potential satisfaction survey of the area's providers and patients.

Product/laboratory review. In examining the product itself—the laboratory—discussion may include the current services of the department, how those services fit into the institution portfolio, the values that providers and patients place on the service, and potential product lines (physician office services, nursing homes, or service centers).

SWOT (strengths, weaknesses, opportunities, threats) analysis. Both external (outside the organization) and internal (inside the organization) factors that will influence the successful implementation of an outreach program need to be considered.

Internal factors are addressed through examination of strengths and weaknesses inside the organization. Strengths need to be supported and maximized, while weaknesses need to be corrected. A weakness could be the inability to determine test costs, thereby inhibiting the establishment of a pricing methodology. A strength is exemplified by the presence of state-of-the-art technology within the testing laboratory. Special consideration needs to be given to factors dealing with specimen transport and processing, information systems including reporting functionalities and remote order entry/reporting, marketing and sales availability, and customer service capabilities.

External factors can be categorized as opportunities or threats. An opportunity is a positive element of the market in which an organization is likely to enjoy superior competitive advantage. A proposed outreach service center location convenient for prospective patients would be an opportunity. A threat is a challenge posed by an unfavorable trend or competitor that would lead, in the absence of purposeful marketing action, to the stagnation, decline, or end of a program or product. An example would be the establishment of a regional reference laboratory within the desired market area by a competitor.

Exploring the Market

Determination of the service or market area may be accomplished by looking at the area from a functional and geographic viewpoint. Within the hospital organization itself, especially if a healthcare system is involved, a determination must be made of what services the core laboratory will provide (and where) as compared to what services Outreach will provide (and where). Some questions to be answered include reporting (who/how), testing services (where/by whom), customer services support (who/what), and specimen processing (how/where/by whom).

The outreach program's service area may be different from that of the hospital or healthcare system. A primary service area (specimen transport within 2 hours of collection) may be structured around local providers such as physicians and home healthcare agencies. A secondary service area (specimen transport within 2 to 24 hours) is best developed after the initial market share involving the primary service area is established.

Market segments need to be identified. There are many resources that can provide demographic information concerning market segments such as physician practices, home healthcare agencies, hospice programs, long-term care facilities, dialysis centers, mental health facilities, occupational health programs, other hospitals, and veterinary practices.

Market segments may be assessed by several methods. Since medical staff physician referrals are the most easily accessible segment and offer the greatest potential return on investment for the beginning outreach program, we will use this segment as an example; however, similar strategies may be utilized with each market segment. Initial focus needs to be on the specialties that usually provide most of the test referrals: Family Practice, Internal Medicine, and Obstetrics/Gynecology. In some markets, Pediatrics and Urology may be added to this list.

Information concerning the community need for outreach laboratory services may be gathered by interviews with 10 to 15 carefully selected physicians and a mail-in survey to all medical staff. Generally, the return on mail-in surveys is about 10 to 15%, but the responses can be improved by active promotion by pathologists and hospital/medical staff committees through individual discussions, a newsletter to local offices explaining the

本书版权归John Wiley & Sons Inc.所有

purpose of the survey, and announcements in hospital or medical society newsletters. Focus groups made up of physician office staff members who regularly interface with a laboratory are also useful. In addition, it is also valuable to identify physicians who, based on their specialties and/or their ability to influence other physicians within the medical community, may serve as champions for the outreach program. The survey questionnaires or interview and focus group guides need to solicit responses about issues related to laboratory testing that are important to the physicians and office staff.

Another useful tool in exploring the market is an image analysis. An organization's image is a function of its deeds (services) and its communication (public relations). It is the organization's image, not necessarily its reality, to which people respond.

Often a questionnaire is used to provide information rating laboratory services including overall satisfaction, price, courier, specimen collection site, telephone communication, testing quality, availability of consultant, request forms, test ordering manual, reports, billing accuracy, insurance plan(s) participation, and computer interface. Each characteristic listed is an image element.

The last step prior to presenting these findings to Administration is to develop an outline for planning. This establishes a planning framework by determining the specific planning steps to be followed, including objectives, environment, approach, course of action, and schedule.

At this point, Administration may be approached with this accumulated information to solicit support for further planning, including a strategic plan, business plan, sales plan, and implementation plan. Without administrative support, both financially and strategically, any outreach program is doomed to fail.

Strategic Plan

Strategic planning entails making intelligent choices in determining future programs and goals. Although it is a continuous process of taking a long view of the planning horizon, it can also involve an immediate response to a sudden shift in circumstances. Planning is important if for no other reason than it forces consideration of how Outreach is going to remain or become a viable entity under different sets of assumptions and circumstances, whether they are related to the government, community, or market.

Strategic planning poses such questions as the program purpose and mission, types of clients/patients serviced in the next year or longer period, major geographic areas next year or in the future, trends in delivery of outreach/hospital services, implementation of major services, possible impacts of changes in funding or demography, alternative services required to handle new situations, how alternative services might change the program, and a definition of the new mission statement.

Once a commitment to strategic planning has been made, a strategic planning team needs to be formed, large enough to represent all outreach stakeholders but small enough for an exchange of ideas. Seven to 10 members is ideal. A common denominator for members should be their problem-solving ability and their knowledge of the market from their own unique perspectives. Suggested stakeholders include representatives from Hospital Administration and Finance, Patient Access or Registration, Billing and Collection Services, Physician Services, Information Systems, Marketing and Public Relations, affiliated hospital services such as Home Health and Hospice, and of course, the laboratory, including Pathology. After completing the strategic plan, this group could easily become the outreach advisory group discussed later in the "Business Plan" section of this chapter. A strategic plan should be considered a "living document"; it should be revisited regularly at leadership meetings, and the progress of accomplishments should be tracked.

The process of strategic planning is best accomplished over a relatively short period to ensure continuity of purpose and participants as well as to maintain the momentum that the process generates in its early phases. Consensus is essential to the implementation of a strategic plan. The plan that evolves from the process should provide a framework for orderly decision making. It should make it possible for problems and services to be examined with a sense of perspective.

An effective strategic plan needs to include the following sections.

1. *Mission statement*. A program's mission statement is its fundamental purpose or reason for existence, and must be compatible with the institution's mission statement.
2. *Goal development*. Based on the information from the industry, situational, and SWOT analyses, strategic goals need to be developed. Goals reflect the results that the outreach program seeks to achieve and are the means for achieving the mission. Goals translate the mission into concrete terms. To be effective, the goals established need to be prioritized and stated in quantitative terms so that progress may be measured.
3. *Strategy formulation*. A strategy is a broad course of action designed to achieve a program's goals and objectives. Strategy formulation is a decision-making activity for choosing between alternative courses of action. Strategies may include focusing on target markets, such as physician offices or long-term care, or deciding what the outreach program's portfolio will include regarding product, price, place, and promotion. A truly effective strategic plan should facilitate the day-to-day decision-making process so that decisions are not agonized over but seem obvious. In addition to defined strategies, a broad timeline needs

本书版权归John Wiley & Sons Inc.所有

to be developed to provide a background for expectations.

4. *Control procedures*. Even the most carefully designed plans require periodic review and revision if results deviate from objectives. The establishment of control procedures ensures that strategic planning is a continuous process. The plan should include a mechanism for evaluating new and ongoing services so that criteria for success are defined before the services are initiated. The plan should include a process for scanning the environment to make sure that the program's strategies and even its mission are still desirable and feasible given changing circumstances.

Business Plan

The administrative structure of the outreach plan is, like the organizational relationship, structured to meet the unique needs of the market.

An advisory group, composed of the same stakeholders involved in the strategic plan plus the outreach director, is often beneficial. In addition to providing feedback about the performance of the outreach program and related activities within the service area from their unique perspectives, these individuals may assist with coordinating services with other hospital departments, monitoring quality assurance and customer/client satisfaction, and providing ideas for future program development based on client needs.

The outreach program is driven primarily by the external customer base, not the internal operations of the hospital or laboratory. It is vital that the outreach director not only be capable of operationally managing the program but also be able to communicate the needs of the clients to Administration. In addition, the director must have prior experience in marketing and sales to be able to successfully balance the needs of the clients with the needs of the outreach operations.

Depending on the size and scope of the planned outreach program, additional administrative or managerial personnel may be needed. Usually, a client services or operations coordinator is needed to supervise the day-to-day activities of the patient service center(s) and personnel, including functions such as order entry and registration, telephone or call center operations, and interaction with the testing laboratory, usually the hospital laboratory. A logistics coordinator may be needed if the number of couriers warrants a supervisor unique to the specimen pickup function. If the service area is large enough to require more than one person to provide adequate client sales and account management, a sales representative may be needed to assist the director. It is often advisable to consider hiring a financial assistant to oversee billing and collections, both client and patient, if that function is done by the outreach program rather than the hospital billing office.

The front-line staff will have the most contact with patients and clients. It is through them that the constituents of the market see the outreach program, and they are the major determinants of what image is formed. Again, depending on the services offered by the outreach program, phlebotomists, couriers, and customer service associates may be needed. Hospital registration, if necessary, may be performed by either the registration department or Outreach, and the function may be combined with the phlebotomy process.

An operational assessment of the facility's and laboratory's abilities to provide the types and level of services defined by the prior market and client needs analyses is absolutely necessary to determine the cost and operational impact that the outreach program will have. In addition to normal service requirements (phlebotomists, couriers [STAT or routine], methods for patient registration, test orders, sample collection and processing, reporting/turnaround times, communications systems, and requisition forms), other considerations include regular and consistent personal client contact, sales literature, complete updated directory of services, customer/client-focused educational programs, competitive fee schedules, and flexible billing options.

Each outreach program is uniquely structured to meet the needs of its targeted market. Not only does this apply to administrative and organizational structure, it also applies to physical arrangement and processes. An example would be the physical layout for specimen processing and testing, which needs to be examined from the outreach viewpoint rather than solely from a hospital inpatient perspective.

A clear, explainable process for the establishment and periodic review of the outreach fee schedule and associated Current Procedural Terminology (CPT) codes must be developed. Without the presence of a competitive fee schedule and correct CPT and diagnosis (International Classification of Diseases [ICD]) coding, an outreach program has little chance for success. The charges developed should be based on marginal, per-test costs, leveraging off the already present capacity and overhead of the inpatient and traditional outpatient (emergency room, ambulatory surgery, observation/day treatment) hospital laboratory. Usually, this means that only the supply and reagent costs of performing the test are used as the foundation of the fee schedule, with no immediate need to include testing personnel costs. The direct costs of operating the outreach program, such as salaries, gasoline, postage, and space rental, and indirect costs, such as education, marketing, and equipment service agreements, need to be added to the test cost. Other indirect facility costs, such as the cost of billing a test, may also be added. Client pricing is based on various volume categories, which can be as

本书版权归John Wiley & Sons Inc.所有

sophisticated as a per-test determination (i.e., volume discounts calculated by number of individual tests) or as basic as a total client volume (i.e., volume discounts calculated by total number of tests). It is imperative that these client volume categories be strictly adhered to so that no hint of inducement is present. Based on the volume figures from the normal forecast done previously, a projection of both the costs and billed revenue needs to be done to assure the profitability of the program.

What are the essentials in financial and revenue cycle support to be successful?

- Knowledgeable and detailed billing and receivables methods must be established (internal or, if necessary, external outsourcing).
- Different fee schedules for inpatient and outpatient fees must be set to the outreach market.
- The best billing structure in accessing payor contracts and negotiating contractual rates must be determined.
- Write-off policy must be set to meet payor, regulatory, and fiduciary guidelines.
- A clear policy should be established that dictates when to send to collections.
- The sales staff should follow up in person when financial statements or collection letters are sent to clients in collections.
- The sales team need to be notified of clients in collections and their payments on a monthly basis to assist in effective communication with the client. This may facilitate payment and engender future utilization of services.

Processes related to compliance issues must be addressed. CLIA and CMS certification is required. Certification by CAP, TJC, or the state may also be necessary. A documented, usable compliance plan must be constructed. As clients are developed, service agreements need to be drafted and approved by the facility's legal department to outline what outreach services are provided to which clients, along with billing requirements. A mechanism to obtain descriptive diagnosis or ICD-10 (International Classification of Diseases, Ninth/Tenth Revisions) codes prior to registration and billing needs to be formulated. Medicare patients must have ABNs and MSPs documented prior to testing. The advent of LCDs and NCDs in addition to LMRPs makes Medicare patient registration and billing even more complex.

Customer service processes need to be developed. Usually, customer service issues relate to client education, client problem solving, quality assurance monitors, quality improvements, and problem reporting.

Marketing and sales functions also need to be examined and assigned. Many hospital laboratories will find marketing and sales to be a new function that may necessitate additional staff, especially for sales, which requires one-on-one contact with the clients, sometimes at very short notice—a requirement not easily addressed by most laboratory managers due to their already full schedules. Sales personnel are usually compensated with a competitive base rate of pay plus clearly defined incentives for accomplishing defined sales objectives.

Essential opportunities to support market awareness within outreach services would include improved communication with current and prospective clients, and increased marketing/timely topic content (the main hospital might be included as co-marketing partner).

Sales Plan

The sales plan not only needs to outline sales expectations such as targeted markets and/or clients, test volume, number of patient contacts/registrations, and billed revenue for the coming year, but it also needs to discuss the sales approach adopted by the outreach program. If salespeople believe that their role is simply to make the sale, they will focus on their own needs rather than the client's needs. On the other hand, if the sales force personnel see themselves as resources and problem solvers, they will focus on the client and will seek ways to meet the client's needs.

There are four basic steps in the sales approach to developing a client.

1. *Relating*. The first step is to build a solid relationship. One way to accomplish this is to communicate the reason for the meeting, how the meeting will proceed, and how both participants will benefit from this meeting.
2. *Discovery*. During the discovery phase, the salesperson needs to uncover all the factors that would affect the client's decision to utilize the outreach services. The outcome should summarize the gap between what the client has and what the client wants.
3. *Advocating*. The purpose of the advocating phase is to assist a client in understanding how the outreach services will aid them in meeting their business needs. The sales force will also develop a stronger, more lasting relationship with the client because they are able to demonstrate appreciation and understanding of the client's problems and needs.
4. *Supporting*. From the first three steps, the salesperson gains the information and develops the client relationship to meet the client's expectations after the sale. Supporting the client is built upon four principles: support the buying decision, manage the implementation, deal with dissatisfaction, and enhance the relationship.

The role of service or value-added elements has never been more important than now. Outreach programs can

本书版权归John Wiley & Sons Inc.所有

no longer rely solely on price or test menu to differentiate themselves from their competitors. Most competing programs offer comparable test menus at similar prices and can quickly copy any innovations. Today, the emphasis is on service, and service is the key business strategy for gaining and keeping the competitive advantage. In addition, more and more clients are not only demanding higher levels of service but are also placing more and more emphasis on value added as the basis for deciding where to look for services and what to retain. In short, this growing emphasis on service means that organizations will rely even more heavily on the quality of their service, the success of their service providers, and the effectiveness of their sales force.

Each prospective client is unique in not only the services they desire but also the rate at which the account may be developed. Some prospects will become clients during the first meeting, while other prospects will require numerous meetings before they reach client status.

Promotional literature is a necessity. It can range from basic (business cards and handbook) to sophisticated. Promotional literature might include some or all of these components: brochure for patients, brief history of outreach program, list of participating insurance plans, sample fee schedule, services handbook, business cards, electronic presentation template, literature folder, fact sheet for clients, list of current clients, sample client service agreement, sample client bill, sample requisition, and proposal cover.

Client profiles need to be built on each prospect by the salesperson and updated upon each contact. The profile will be the complete story about each prospect/client, from initial contact to current or most recent sales interaction. The minimum information that should be contained in the client profile can be seen in Table 37.2.

Table 37.2 Minimum information that should be contained in the client profile

Provider/physician name
Mailing address
Voice phone number
Specialty
Hospital affiliations
Original service agreement date
Method of reporting results
Organization name
Pickup/delivery address
Fax number, email address
Contact person and position
Beginning service date
Last service agreement renewal date
Check-off of equipment issued

Communication about sales activity is vital to the coordination of an integrated outreach program. It is the responsibility of the salesperson to keep Outreach management and personnel informed of prospect development and client relations. In addition, it is the salesperson who will play a major role in coordinating the outreach program's sales efforts with other areas of the hospital or health system that are also involved in sales. A monthly report of sales activity may facilitate the communication. The report should also include new client prospects, visit summaries for current clients, and any issues of importance.

It will then be time to put together a budget based on the people, processes, equipment, facilities, and fee schedule. Most hospitals already have a budget template that may be used. Usually, additional expense categories that may not be routinely addressed by the facility need to be developed, including marketing/sales/public relations, rent, gasoline, utilities, postage, printing, billing services, and courier services.

In concert with the budget, a cost-benefit analysis must be done to look at the expected profitability of the program, including the test volume and revenue (sales), both billed and collected, that are needed for the program to break even.

Commitment from All Relevant Parties

Feasibility Report

Final commitment for the outreach program from the facility's administration must be solicited before implementation can occur. A feasibility report or business plan, based on the data previously acquired, provides valuable information for the administration to use in making the "go or no-go" decision. The report is a summary of the market and service assessments, the cost/benefit analysis, operational options, and recommendations.

Philosophical Understanding

Commitment from Administration must not only provide financial and human resource support; it must also provide a philosophical understanding of the plans and goals of the outreach program and how it fits into the overall organizational plan—both short term and long term. Administration must also have a clear understanding of the nature of the volatile outpatient outreach industry and how it differs from the traditional inpatient hospital industry.

Service and Financial Support

The Administration commitment should include service support for issues related to information services, marketing, sales, and billing and collections. Once this commitment is firmly in place, it is time to plan the implementation of the outreach program.

本书版权归John Wiley & Sons Inc.所有

Implementing the Outreach Program

No one part of the implementation plan is more important than any other. Each is integral to a successful startup. Use of some sort of project management software is strongly suggested due to the complexity of the coordination needed.

People

Recruitment must follow job description development, not precede it. Training programs need to adequately prepare the people for the positions they will be taking, and are an investment in the future operational efficiency of the outreach program. Inadequate training often leads to increased error rates, patient and client dissatisfaction, and employee dissatisfaction. Competency testing, mandated by several accrediting organizations, is the documented story of training success. One example involves the physician and nursing home business, where success depends on the ability to recruit and maintain superbly trained phlebotomists.

Processes

The processes that the outreach program will use need to be consciously thought out, documented, and communicated, not only to the outreach people hired but also to interfacing departments such as the laboratory staff, Information Systems, and Billing—possibly through a series of presentations outlining the program development. Workflow, including physical layout and process steps, needs to be developed and documented. The use of flow charts can point out redundant steps and bottleneck points. Policies and procedures must be written and shared with all involved staff. Planning and implementation of a process improvement program, including quality control, quality indicators, quality improvement, and compliance audits, is necessary in addition to processes related to patient and client services.

Facilities

Depending on the goals and size of the outreach program, some attention will need to be paid to the facilities in which the people and processes will be functioning. Many organizations have personnel within their engineering or facilities management departments who may be helpful. Issues to be considered include whether separate service centers are needed, and if so, their location, size, and space needs, the necessity for construction or renovation, and the requirements for the location (e.g., utilities, access for patients and couriers, parking). Further, assets and resources to present the services to clients, patients, and the community as a whole must be made available.

Equipment

The equipment required, like the facilities required, will be unique to each outreach program. Decisions are required for each program when evaluating equipment for information services, technical areas (such as phlebotomy chairs or telephone systems), testing (waived or more complex testing), and specimen transport (contracted courier services or the facility's own). The materials management department may be able to assist in those selections, and many organizations have already existing contracts with multiple vendors. Importantly, installation and training, as well as repair, need to be considered in equipment selections.

Supplies

Most outreach programs not only stock supplies for their own use, but they also provide supplies at no charge for clients to use in collecting specimens that will later be sent to the outreach program. The OIG of CMS has issued a fraud abuse alert specifically on this subject. Supplies may be provided free of charge to clients only if those supplies are used exclusively for the collection of specimens sent to the outreach program providing those supplies. Supplies such as tourniquets or syringes that may be used for procedures other than venipuncture may not be provided free because they are not exclusive to venipunctures. Issues include the ordering and delivery of supplies (by whom, to whom) and monitoring of client supply use.

Outreach Indicators

Once the outreach program is up and running, it is time to monitor its performance by developing outreach indicators. To date, there is very little in the literature concerning outreach benchmarking, so it is difficult for one program to assess how it compares to other programs. However, month-to-month progress can be tracked in terms of service, finance, efficiency, and sales (Table 37.3).

Growing the Outreach Program

Pursuing laboratory outreach expansion opportunities should be accompanied by objective goals with specific and measurable outcomes. When a laboratory can support and contribute to mission-aligned growth of the enterprise, it continues to be an opportunity to reassess issues like cost, revenue, and staffing.

Assessment

The headlong entry of a business endeavor into an oversaturated market often ends in failure. Awareness of the local and national healthcare industry, as well as of laboratory operating costs, is a key factor to determine prior to launching any outreach or expansion endeavor. A laboratory that is

本书版权归John Wiley & Sons Inc.所有

Table 37.3 Outreach indicators

Service
Customer satisfaction surveys
Clinical errors
Missed specimen pickup
Days in Accounts Receivable
Telephone call center summary
Finance
Cost/revenue per patient contact
Test volume
Test cost-to-charge ratio
Net collections
Tests per requisition
Efficiency
Patient wait times
Test-to-report turnaround time
Staff hours per patient contact
Ratio of patients to specimens
Sales
Pipeline report
Current client visit summary
Client billing report

not operating at its maximum capacity becomes more expensive to maintain and is unable to optimize costs. Also, as declining reimbursements continue to be a consideration, increased test volumes and managing costs can support the laboratory to remain profitable. A third issue for consideration involves personnel, particularly within this era of staff shortages and burnout. Adding more work to the mix may seem counterproductive; however, growth initiatives can include improved technology, an expanded test menu, additional/improved automation, and additional staff. The emphasis on new approaches to the work can motivate the staff, especially when taking on new challenges within a growing laboratory environment. Staff remain a facility's most important asset; feeling challenged and appreciated can enhance the overall success of the organization.

Client Needs

Development and implementation of a successful outreach program cannot be haphazard or casual. It is not something that a laboratory does in its "spare time." It is a business and must be operated as such. It must be customer focused. Services and processes must be structured from the customer's point of view rather than from a traditional, inpatient laboratory viewpoint. Once this is accomplished, the successful laboratory outreach program is an asset not only for the parent facility but also for the community it serves. Each laboratory outreach program is unique, depending on the needs of its customers, the market environment, and the resources available. The structure and processes of the outreach program must be designed to meet those evolving needs for sustained success. The successful outreach program contains a strong yet flexible infrastructure constructed to meet the ever-changing client needs through efficient processes, placement of the right people in the right jobs, and strong commitment to the program from hospital administration.

SUMMARY

As the healthcare industry continues to face many challenges, the clinical laboratory shares these same challenges. A laboratory outreach program provides opportunities to support and participate within the community, as well as supporting the overall institutional expansion goals. The laboratory's contributions to this effort provide and enhance valuable patient care services that support the total enterprise.

KEY POINTS

- Several issues must be considered prior to obtaining administrative commitment for the implementation of an outreach program. These include determination of administrative interest, a thorough exploration of the market potential, and development of potential strategic, business, and sales plans.
- Once a detailed feasibility report has been reviewed and discussed by all relevant parties, then there should be some confirmation of philosophical understanding and service and financial support required from all parties, particularly the administration.
- Detailed plans related to people, processes, facilities, equipment, and supplies must be developed and reviewed by all relevant personnel and then implemented using a detailed timeline.
- Indicators for ongoing assessment of the program's progress must be reviewed on a continuous basis, with anticipated growth being a critical component of the plan.

GLOSSARY

Advanced Beneficiary Notice (ABN) Advises Medicare beneficiaries, before items or services are actually furnished, when Medicare is likely to deny payment for them.

Business plan A financial and operational analysis of the feasibility of the implementation of a program.

Centers for Medicare and Medicaid Services (CMS) A federal agency within the U.S. Department of Health and Human Services that runs the Medicare program, Medicaid program, and State Children's Health Insurance Program (SCHIP).

Clinical Laboratory Improvement Amendments (CLIA) CMS regulates all laboratory testing (except research) performed on humans in the United States through CLIA. In total, CLIA covers approximately 175,000 laboratory entities. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations has the

本书版权归John Wiley & Sons Inc.所有

responsibility for implementing the CLIA program. The objective of the CLIA program is to ensure quality laboratory testing. Although all clinical laboratories must be properly certified to receive Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities.

College of American Pathologists (CAP) The principal organization of board-certified pathologists, CAP serves and represents the interests of patients, pathologists, and the public by fostering excellence in the practice of pathology and laboratory medicine.

Cost-benefit analysis A projection of the resources needed to implement a program and the benefits derived from such a program.

Equal Employment Opportunity Commission (EEOC) The EEOC was established by Title VII of the Civil Rights Act of 1964 and began operating on July 2, 1965. The EEOC enforces the following federal statutes:

- Title VII of the Civil Rights Act of 1964, as amended, prohibiting employment discrimination on the basis of race, color, religion, sex, or national origin
- The Age Discrimination in Employment Act (ADEA) of 1967, as amended, prohibiting employment discrimination against individuals 40 years of age and older
- The Equal Pay Act (EPA) of 1963, prohibiting discrimination on the basis of gender in compensation for substantially similar work under similar conditions
- Title I and Title V of the Americans with Disabilities Act (ADA) of 1990, prohibiting employment discrimination on the basis of disability in the private sector and state and local governments
- Sections 501 and 505 of the Rehabilitation Act of 1973, as amended, prohibiting employment discrimination against federal employees with disabilities
- The Civil Rights Act of 1991, providing monetary damages in cases of intentional discrimination and clarifying provisions regarding disparate impact actions

Food and Drug Administration (FDA) The FDA Modernization Act of 1997 (PL 105-115) affirmed the FDA's public health protection role and defined the agency's mission:

- To promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner
- With respect to such products, to protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled; that human and veterinary drugs are safe and effective; that there is reasonable assurance of the safety and effectiveness of devices intended for human use; that cosmetics are safe and properly labeled; and that public health and safety are protected from electronic product radiation
- To participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements
- As determined to be appropriate by the Secretary, to carry out the items above in consultation with experts in science, medicine, and public health and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products

International Classification of Diseases, Ninth Revision (Clinical Modifications) (ICD-9-CM) Based on the official version of the World Health Organization's ICD-9, which classifies morbidity and mortality information for statistical purposes, for the indexing of hospital records by disease and operations, and for data storage and retrieval.

Image analysis An evaluation of the customer's beliefs, ideas, and impressions of an organization.

Industry analysis An evaluation of an industry that recognizes unique factors within the industry that have an impact on the survival of an organization. It includes barriers to entry, determinants of supplier power, determinants of substitution threat, determinants of buyer power, price sensitivity, and rivalry determinants.

The Joint Commission (TJC) Evaluates and accredits nearly 17,000 healthcare organizations and programs in the United States. An independent, not-for-profit organization, TJC is the nation's predominant standards-setting and accrediting body in healthcare. TJC's evaluation and accreditation services are provided for the following types of organizations:

- General, psychiatric, children's, and rehabilitation hospitals
- Critical-access hospitals
- Healthcare networks, including managed-care plans, preferred-provider organizations, integrated delivery networks, and managed behavioral healthcare organizations
- Home care organizations, including those that provide home health services, personal care and support services, home infusion and other pharmacy services, durable medical equipment services, and hospice services
- Nursing homes and other long-term-care facilities, including subacute-care programs, dementia special-care programs, and long-term-care pharmacies
- Assisted-living facilities that provide or coordinate personal services, 24-hour supervision and assistance (scheduled and unscheduled), activities, and health-related services
- Behavioral healthcare organizations, including those that provide mental health and addiction services, and services to persons with developmental disabilities of various ages, in various organized service settings
- Ambulatory-care providers, for example, outpatient surgery facilities, rehabilitation centers, infusion centers, and group practices, as well as office-based surgery
- Clinical laboratories, including independent or freestanding laboratories, blood transfusion and donor centers, and public health laboratories

Local Medical Review Policies (LMRPs) Local policies outline how contractors will review claims to ensure that they meet Medicare coverage requirements. The CMS requires that LMRPs be consistent with national guidance (although they can be more

本书版权归John Wiley & Sons Inc.所有

detailed or specific), developed with scientific evidence and clinical practice, and developed through certain specified federal guidelines. Contractor medical directors develop these policies.

Marketing Determining the customer's needs and wants.

Market segment A portion of the market where consumers share a group of common characteristics.

Medicare Secondary Payor (MSP) A Medicare provider, whether a physician, nonphysician practitioner, laboratory, or other supplier (durable medical equipment supplier, etc.), is required to indicate if there is other insurance that may be primary to Medicare when submitting a Medicare claim for payment. The purpose of this questionnaire is to determine whether Medicare or the other insurance has primary responsibility for meeting the beneficiary's healthcare costs. The goal of these MSP information-gathering activities is to identify MSP situations rapidly, thus ensuring correct primary and secondary payments by the responsible parties.

National Coverage Decision (NCD) An NCD sets forth whether Medicare will cover, or not cover, specific services, procedures, or technologies on a national basis. Medicare contractors are required to follow NCDs. If an NCD does not specifically exclude an indication or circumstance, or if the item or service is not mentioned at all in an NCD or in a Medicare manual, it is up to the Medicare contractor to make the coverage decision (see Local Medical Review Policies).

Occupational Safety and Health Administration (OSHA) The mission of OSHA is to save lives, prevent injuries, and protect the health of America's workers. OSHA and its state partners have approximately 2,100 inspectors, plus complaint discrimination investigators, engineers, physicians, educators, standards writers, and other technical and support personnel spread over more than 200 offices throughout the country. This staff establishes protective standards, enforces those standards, and reaches out to employers and employees through technical assistance and consultation programs.

Office of Inspector General (OIG) The mission of the OIG, as mandated by Public Law 95-452 (as amended), is to protect the integrity of Department of Health and Human Services programs, as well as the health and welfare of the beneficiaries of those programs. The OIG has a responsibility to report, to both the Secretary and the Congress, program and management problems and recommendations to correct them. The OIG's duties are carried out through a nationwide network of audits, investigations, inspections, and other mission-related functions performed by OIG components.

Operational assessment An evaluation of the organization's ability to provide the types and levels of services defined by prior market needs.

Situational analysis Description of the major features in a local environment that affect an organization; includes a background, current activity, normal forecast, market description, and product review.

Stark legislation The Stark legislation prohibits a physician from referring his or her patients to entities with which the physician or his or her family members have a financial relationship, such as an ownership interest or compensation arrangement. The initial Stark legislation, known as Stark I, was enacted in 1989 and applies only to clinical laboratory services. In 1993, Congress enacted the Stark II legislation, which extends the prohibition to referrals made by a physician to an entity for the furnishing of "certain designated health care services" if the physician or his or her family member has a financial relationship with that entity.

Strategic plan Documentation of a process that develops the organization's future goals and programs within the context of a changing industrial and market environment. The plan includes a mission statement, goal development, strategy formulation, and control procedures.

SWOT analysis An evaluation of internal (strengths, weaknesses) and external (opportunities, threats) factors that may influence the successful implementation of a program.

Target market The market segment(s) chosen by the organization to focus on.

ACKNOWLEDGMENTS

The authors are grateful for the contributions by Charlene H. Harris to this chapter in the 2nd edition of *Clinical Laboratory Management*.

REFERENCES

1. **Hermansen J.** 2019. How outreach programs help labs achieve financial stability. Today's Clinical Lab. https://www.clinicallab.com/how-outreach-programs-help-labs-achieve-financial-stability-217. Accessed 4 February 2023.

2. **Murphy K.** 2016. The profit machine in the hospital basement: turning your lab into an economic engine. Accumen (CHI Solutions, Inc. DBA Ellsworth Press), Scottsdale, AZ.

3. **Collins J.** 2011. *Good to Great: Why Some Companies Make the Leap and Others Don't*. HarperCollins Publishers Inc, New York, NY.

4. **Kotler P** (ed). 2008. *Strategic Marketing for Nonprofit Organizations*, 7th ed. Prentice-Hall, Inc, Englewood Cliffs, NJ.

5. **Nigon DL**. 1997. *Within Your Reach: a Manual for Developing a Laboratory Outreach Program*. Clinical Laboratory Management Association, Inc, Wayne, PA.

6. **Romig DA**. 2002. *Side by Side Leadership*. John Wiley & Sons, Somerset, NJ.

7. **Hermansen JM**, **Hiltunen MJ**. 2016. Survival strategies for laboratory outreach programs. Medical Lab Management. https://www.medlabmag.com/article/1250/March_2016/Survival_Strategies_for_Laboratory_Outreach_Programs. Accessed 4 February 2023.

8. **Hiltunen MJ**, **Kolozsvary J**, **Bohlender D**. 2020. The benefits of network participation for laboratory outreach. Medical Lab Management. https://www.medlabmag.com/article/1624. Accessed 4 February 2023.

9. **Hermansen JM**. 2021. Become the outreach laboratory of choice. Medical Lab Management. https://www.medlabmag.com/article/1801. Accessed 4 February 2023.

10. **Shinkman R**. 2016. Is the value to hospital lab outreach underrated?CAPTODAY.https://www.captodayonline.com/value-hospital-lab-outreach-underrated/. Accessed 4 February 2023.

本书版权归John Wiley & Sons Inc.所有

38

Introduction
The Clinical Laboratory as a Business • The Phases of the Growth Curve
Decision Making in Laboratory Outreach Management
Types of Costs
Direct and Indirect Costs • Fixed, Variable, and Semifixed Costs • Unit Costs • Additional Cost Concepts for Decision Making • Characteristics of Laboratory Costs • Microcosting • Beyond the Laboratory Test Cost
Levels of Decision Making in Outreach Operations
Menu: To Test or Not To Test • Operation: To Perform In-House or Send Out • Capital: Whether To Acquire New Equipment • Financing Capital: To Lease or Buy Equipment
Financial Considerations in Outreach
Role of Metrics-Based Decision Making • Realization Rate • Direct Client Billing and Accounts Receivable
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENT
REFERENCES
APPENDIXES

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch38.

Finance and Decision Making in Outreach

Ziad Peerwani

OBJECTIVES

To provide background on some basic financial concepts related to operational and strategic decision making in laboratory outreach and the logic behind them

To provide formulas and worked examples of calculations in the appendixes

I can make more generals, but horses cost money.

Abraham Lincoln

Introduction

The Clinical Laboratory as a Business

On a macro level, healthcare exists in a state of financial scarcity, translating into persistent financial pressure. This exists regardless of setting, be it academic, nonprofit, government, or commercial. This scarcity raises the question of how limited resources are utilized to the greatest advantage within various systems. These pressures persist within the laboratory, influencing decisions and strategy.

As a business, the clinical laboratory is unique and complex, sharing the economic characteristics of both a service business and a manufacturing industry (1–6). It is a service industry that is nonetheless responsible for a product: clinical information. The production of laboratory data requires a heavy investment in assets such as scientific instruments, advanced facilities, and trained personnel. This heavy endowment of assets is more typical of manufacturing firms. The laboratory's service is characterized by an extremely short service turnaround time compared to many other service industries. Clinical laboratory operations (particularly those that are "24/7") require a more constant and demanding management of human and financial resources than does the average service business.

It is often overlooked that laboratory work can have a seasonal component, as, for example, when setting up assays for influenza. When found to be present, seasonality should be an important planning factor, especially in efforts to deploy the usually limited human and financial resources.

Constant technological innovation characterizes the clinical laboratory to a greater extent than in many other service industries. The frequent changes and improvements in techniques and methods of producing laboratory results create much uncertainty in the acquisition of equipment and material, which may have a relatively high rate of obsolescence.

本书版权归John Wiley & Sons Inc.所有

As laboratories grow to accommodate healthcare systems or hospital needs, they invariably build in unused capacity to buffer against shifting demand. The resulting unused labor force and testing capacity represent a potential revenue stream in the right setting or waste if they remain unused. From a typical healthcare perspective, laboratory volumes are typically restricted to hospital or system patient volumes. Clinical service expansion drives laboratory growth. Therefore, the laboratory has little leverage to directly influence volume growth. Since it cannot improve volumes or increase revenue, its only recourse to improve financials is cost containment. Although an important endeavor, persistent and extensive focus on cost containment creates a negative working environment and increased difficulty for management.

An option for laboratories is leveraging unused capacity to serve the broader community, supporting external clients through an outreach laboratory program. In this setting, testing growth is dissociated from institutional clinical growth. The lab creates a sliver of control over its volume growth while supporting the institution financially. The laboratory now has an alternative to cost-cutting targets, potentially mitigating financial pressures through revenue generation.

For most outreach laboratories, external client volume represents a small portion of total operational volume. Many outreach services begin as an offshoot of an established hospital or healthcare system laboratory. With time, the service may grow, justifying a stand-alone lab to service outreach work. Nonetheless, the hospital's or healthcare system's volumes typically overshadow the outreach service volumes.

Therefore, decision making within the lab, particularly with regard to staffing and instrumentation, is dictated by the institutional volume. The outreach volume, although representing an additional or even important revenue stream, is often a secondary driver for operational decisions. It is inevitable that conflicts will arise, potentially impacting the outreach business. Robust communication between the outreach service and laboratory operations is imperative to support the business without jeopardizing patients, the institution, or the external clients.

The influence of institutional volumes extends to financial considerations, metrics, and decision making, as they pertain to the outreach laboratory. The outreach business is a shift from the traditional laboratory. In order for the outreach unit to be successful, its approach to finance as well as back office function must adapt to meet market and client needs. In addition, how the finances are reviewed, metrics defined, and decisions made are different from a typical laboratory decision-making process.

The Phases of the Growth Curve

A product, technology, firm, or industry is said to evolve through phases of development, during which aspects of its economics may change. The initial or startup phase is a time when the new venture is usually not profitable, and its rate of growth is sluggish at first. This is the phase in which many laboratory or product failures occur. Financial planning for this phase is inherently difficult and challenging because of the number of uncertainties involved.

The growth phase is the phase of fastest expansion and the greatest operational challenge, when a laboratory venture breaks even or a product begins to pay off. The chance of its long-term survival is considered much improved if it has successfully weathered this phase. Financial planning during this phase is exciting because of the unusual growth rate, though some residual uncertainty remains.

During the mature phase, typically operational pains are no longer as great and the rate of growth has decreased. When a laboratory or product reaches this stage, its prospects for survival in the market are favorable. Financial planning becomes routine and continuous.

The declining phase is the phase of negative growth, which presents a special challenge. At the least, it should be anticipated so that it will trigger a search for a new product or technology. The clinical laboratory industry as a whole has often been portrayed as being in the mature phase currently, though foreseeable changes in technology may modify this assessment one way or the other.

Given all of the clinical laboratory's special characteristics as a business, and given the fundamental dynamics of change in the contemporary U.S. healthcare industry, the ongoing challenge is to provide lower prices and easy access to services while reducing *per capita* costs and maintaining high standards of quality. As more decisions about the cost and volume of health services to be delivered move from the physician and hospital to the purchasers of care, both hospital and physician office clients have focused energy on accounting for and managing costs. The economic mission of the hospital laboratory has shifted from revenue generation *per se* to managing the cost side of the equation. Hospital laboratories have increasingly replaced labor with technology, dealt creatively with productivity issues, and merged, consolidated, regionalized, and formed joint ventures to achieve economies of scale.

Decision Making in Laboratory Outreach Management

Outreach potentially represents an alternative approach to ensure the survival of the hospital clinical laboratory in the midst of unparalleled industry change. The transition to outreach, however, represents a true change of culture, in that price competition, external service demands, and the quest for market share vie with and may supplant certain of the internal preoccupations of traditional hospital-focused laboratory management. Unlike the typical

本书版权归John Wiley & Sons Inc.所有

laboratory, more of the decision making within the outreach unit has a distinctly financial character.

Clinical, scientific, and technical issues remain key considerations within the outreach business. Despite considerable financial drivers, understanding how to appropriately balance patient versus financial issues is key to a successful outreach program. The quality of testing and clinical support reflects the underlying value of testing and the organization. Outreach clients recognize this value, resulting in brand equity. Nonetheless, financial considerations remain a key decision driver, reflecting both lab operations and outreach management.

Types of Costs

Direct and Indirect Costs

Direct costs are all costs that can be specifically linked to a test. Examples of direct costs include technical, supervisory, and clerical wages; overtime; on-call payments; and chemicals and supplies related to the test. Service costs are direct costs that are incurred as tests are performed. They represent variable costs plus those fixed costs that are most directly traceable to the testing. The service cost concept is useful in budgeting and analyzing cash flow.

Indirect costs (or overhead) are all costs not directly traceable to the test but included in the total laboratory expenses. Examples of indirect costs include depreciation, building and equipment maintenance, insurance, utilities, housekeeping, and purchasing and billing services, as well as sales, marketing, and development costs. Many indirect costs are period costs, i.e., costs that represent fixed outlays for the whole laboratory or the whole hospital per unit time for outreach operations that are integral with hospital laboratories. The details of the allocation formulas by which hospital administration assigns indirect costs from the general hospital operation to the outreach laboratory operation can be the deciding factor in understanding the true profitability of lab outreach. These allocation rules must be explicit, well justified, and mutually agreed upon at the outset for laboratory outreach to have any hope of success.

Fixed, Variable, and Semifixed Costs

Fixed costs remain unchanged for a given period of time, despite changes in test volume. Examples of fixed costs include supervisory and custodial wages and benefits, required regardless of volume, as well as depreciation of the building, space, and equipment. Variable costs change in more or less direct proportion to test volume. Examples include testing reagents, disposable supplies, and forms.

It is appropriate to regard some costs as semifixed or mixed costs, since costs are fixed over a range of volumes but increased after a certain point. Although we often see labor cost as variable, technical labor force cost is often a semifixed cost within the modern laboratory. Each full-time employee (FTE) can manage a certain number of tests per year. The volume has to exceed their capacity before additional staff are hired. Therefore, additional labor costs are fixed until sufficient volume exceeds capacity, warranting an additional hire. Once hiring is done, the labor force cost becomes fixed until the individual's capacity is once again exceeded.

The outreach laboratory often leverages unused capacity, including technical and labor force capacity. If this is the case, labor force and instrumentation costs may be considered relatively fixed depending upon the volume contribution. Management and the financial team will have to work together to better understand how external workflow contributes to cost structures. This can have an important impact on pricing strategies, particularly within a competitive marketplace.

Unit Costs

Unit costs are the costs per unit of production or unit of service provided, accountable as fixed and variable costs per unit. Variable cost per unit generally remains the same regardless of volume. As volume increases, the total variable cost increases by the same percentage, yet on a per-unit basis, the variable cost remains unchanged. Fixed cost per unit is generally reduced as the total fixed cost is spread over more tests. Total fixed costs remain the same regardless of volume increases, whereas on a per-unit basis, they decline. Economy of scale means that the higher the volume of tests, the lower the overall unit cost.

It is important to be able to differentiate the varieties of unit costs that occur in clinical laboratory operations. Cost per test (or cost per result) is typically the total of the direct (both fixed and variable) costs, as well as allocations of certain of the "more direct" indirect costs associated with the production of a single individual-analyte test result: reagents, disposable supplies, equipment, and labor. Cost per reportable result includes the same costs not only for the individual-analyte test result itself but also for all the quality control, calibrator, waste, and repeat results necessary to be able to report that result. Cost per billable result accounts for the costs of all the reportable results that are included in a unit of service, such as a test panel or battery, that is made up of multiple individual-analyte results but billed as a group; i.e., a 12-test panel counts as 1 result unit, not 12. Cost per relative value unit (RVU) applies to certain results, like surgical pathology reports, that have a labor component involving significant professional time spent on cognitive interpretative tasks. For such results, various systems of RVUs have been devised and implemented by professional organizations to account for these activities in order to bill for them. The laboratory costs associated with these billables can be accounted as cost per RVU.

本书版权归John Wiley & Sons Inc.所有

Additional Cost Concepts for Decision Making

Costs can be accounted in a variety of ways, and the particular cost concepts used in a given situation may differ depending on the nature of the decision to be made, i.e., planning and budgeting, reporting, or monitoring and feedback. Each cost concept thus has a task-specific usefulness.

Out-of-pocket costs represent cash outlays made at or close to the time of a given activity. Timing of cash flows in capital transactions may have out-of-pocket costs as important considerations in decision making. In contrast to out-of-pocket costs, book costs reflect allocations of past outlays to the current period and have more limited usefulness in budgeting and capital decision making.

Historical costs are actual cash payments accounted for and recorded at the time of outlay. They are used extensively in external reporting and represent what are also called sunk costs, since they are not changeable by any management decision and have importance mainly in forecasting trends. Future costs, both fixed and variable, direct and indirect, on the other hand, have the potential to be changed by current decisions and thus represent the most appropriate focus for planning efforts, like budget and capital acquisition decisions.

Differential or incremental costs represent the change in future fixed and/or variable costs resulting from specific courses of action. A special case is the unit incremental or marginal cost, which is the cost of adding one unit of production. Total costs represent the sum of these incremental costs plus costs that do not change due to the course of action being considered.

Opportunity costs represent benefits that may be missed as a result of rejecting a more profitable alternative use of resources (materials, labor, facilities, or capital) when making a decision. They represent lost revenue, not expenditure, and they are variable costs whose amounts depend on the alternatives under consideration. Imputed costs are all costs (including opportunity costs) that do not involve outlay of cash. An example might be depreciation of capital equipment. For capital expenditure decisions and in other situations in which investment alternatives are being considered, opportunity and imputed costs become useful concepts. They are not explicitly listed in accounting records but must be derived.

Controllable costs are fixed or variable costs that can be influenced by a specific individual's decision making. Noncontrollable costs are outside the scope of a specific individual's control. The concepts of controllable and noncontrollable costs are useful in evaluating individuals' performance in terms of fiscal accountability. Thus, the statement that an executive has "P and L" (profit and loss) responsibility for any portion of the operation implies that all of its costs are controllable, either directly or indirectly, by that individual. Table 38.1 compares various types of costs.

Table 38.1 Comparisons of different types of costs

Dimension	Cost	Characteristics	Examples	Related concepts
Operational traceability	Direct	Traceable to production of individual tests	Reagents, supplies, technical wages	
	Indirect	Not directly traceable to production of individual tests	Utilities, capital, maintenance, marketing and sales expenses	Overhead
Volume behavior (may be direct, indirect, or a combination)	Fixed	Total remains unchanged regardless of test volume	Supervisory wages, rent	
	Variable	Total changes with test volume	Reagents, disposable supplies	
	Mixed	Hard to classify with regard to volume behavior	Clerical wages, IT costs	
Denominator (may be direct, indirect, or a combination)	Incremental	Accounted per unit of production	Cost per test	Marginal cost, unit cost per: result, billable, RVU
	Period	Accounted per unit of time	Annual cost	
Cash flow impact (may be direct, indirect, or a combination)	Out of pocket	Involves outlays of cash during production	Supplies, reagents, salaries, utilities	
	Imputed	Incurred in ways other than direct cash outlays	Capital payback, depreciation, inflation	Historical costs, sunk costs, book costs
Accountability (may be direct, indirect, or a combination)	Controllable	Influenced by individual lab manager's decisions	Reagents, supplies, overtime	Opportunity costs
	Noncontrollable	Not usually influenced by individual manager's decisions	Benefits, utilities	

本书版权归John Wiley & Sons Inc.所有

Characteristics of Laboratory Costs

Fixed costs constitute a large proportion of overall cost in a typical clinical laboratory. This fact has implications for certain key decisions, such as those involving analyses of cost, volume, and margin interrelationships. It also means that in a typical hospital laboratory, the range of alternatives may be limited by the fact that a change in volume does not necessarily result in a directly corresponding change in costs. The existence of this phenomenon may, on the other hand, create an opportunity for outreach in terms of the potential for utilizing the *de facto* marginal excess production capacity these necessary fixed costs may represent when viewed from the outreach perspective. An example might be expanding volume during off shifts in a three-shift operation to "fill the factory" 24 hours per day.

Microcosting

It is essential that an outreach laboratory account explicitly for all direct and indirect costs of production. Ideally, each test on its menu should be microcosted to account for each category of expense involved in the production of each unit of service at the test volume at which the laboratory is operating. Microcosting can be either bottom-up (built up from known unit-cost inputs; also known as job order costing) or top-down (unit costs estimated from aggregate expenses divided by units of service; also known as process costing). Either way, the availability or nonavailability of cost data by areas or tests may restrict the analysis of cost behavior. Microcosting using the bottom-up (job order) costing methodology involves four important aspects: labor costing, material costing, other costing (overhead and equipment costs), and the detailed analysis of those costs over the relevant range of volume produced in various production runs.

For labor costing, it is important to determine the real labor cost per hour. Not only should the nominal hourly rate paid be taken into account, but so should the fringe benefit cost rate per hour. Usually this is stated as a percentage of the hourly labor cost, e.g., 28.8% of labor costs added to the nominal hourly rate. This hourly rate must be further adjusted by actual available hours versus potential hours per year (potential hours per year is usually stated as 2,080 hours, calculated as 52 weeks times 40 hours per week). In other words, potential hours must be adjusted to available hours by taking into account the hours accounted for by holidays, vacations, and sick leave. Depending on the laboratory, this can drive down the available hours by 10 to 23%, thus driving up the hourly rate proportionately. Finally, the hourly rate must be adjusted by the production hours (time spent on producing tests or other outputs) versus available hours. Available hours can be reduced by the two 15-minute breaks provided each day, meeting times to discuss objectives, and other important matters, such as continuing education provided on work time. The model in Appendix 38.1 provides a range of production hours from 60% to 100% depending on the judgment of the supervisor after taking into account the variables above. The production rate is the real labor cost per hour.

In terms of material costing, it is important to review the production process in great detail to ensure that all the supplies are taken into account. Their unit costs can be determined by reviewing the suppliers' invoices. It is important to remember to translate the units purchased (packages, boxes, etc.) into the units consumed in production and adjust the unit cost appropriately. In addition, it is important to divide those costs into the fixed portions over the batch and the variable portions over that same batch.

For other costing, overhead and equipment costs (maintenance and depreciation) must be taken into account to move to full costing. This may be accomplished using many different methods. In the methodology illustrated in Appendix 38.1, this is done by adding a percentage of the direct costs for both overhead and equipment costs.

In terms of the detailed analysis of costs over a relevant range of production volume, it is important to distinguish cost components as variable or fixed. The model presented here starts with a batch size of one and ranges up to a typical average batch size and beyond. This method allows the lab to determine cost points and pricing points given a particular customer's needs and demands. If an average price at the expected volume is used and an order for a small set of samples is received, a net loss may result. However, given cost and pricing points, negotiations with the customer may result in an agreement to send in a larger volume at a time in exchange for substantially reduced pricing. This pricing methodology is especially important in price negotiations on testing for research clients.

Beyond the Laboratory Test Cost

When operating an outreach program, additional cost considerations beyond the test unit cost should be taken into account. These could be categorized as preanalytic/support, front office, and back office costs. Not all outreach programs will invest in these areas to the same degree. Smaller programs will not require a sizable investment, while others will face more substantial costs depending upon the scope and volume of outreach work.

In order to compete against large commercial laboratories, outreach programs must become adept at meeting client needs and expectations. Although outreach labs provide high-quality testing, they often struggle with logistics, interfaces, IT (information technology) support, and the like. The client-facing or business delivery side of testing is outside the scope of the typical hospital-embedded laboratory. From a preanalytic and support service perspective, an outreach program will provide varied degrees of services to clients depending upon local market and client needs. At the lower-cost end, outreach

本书版权归John Wiley & Sons Inc.所有

programs may provide transport, requisitions, and some form of resulting. However, some programs provide additional support, extending to in-office phlebotomy, interface ordering and results, portals, technical data updates, collection tube supplies (particularly esoteric supplies and sample kits), and more. Larger outreach programs may consider opening stand-alone phlebotomy centers within their regions to better serve their community. In addition, outreach programs may consider additional client-facing roles to better support business functionality. An example is client support services whose role may include triaging customers' initial queries, solving specific problems, and mitigating customer frustration.

Although faxing remains quite prevalent, interfacing and modernization of the technical infrastructure is an important tool for outreach programs. Increasingly, clients expect interfacing electronic solutions as a key selection criterion for a lab provider. Additionally, patients are becoming more technology savvy, with patient portals and access to their results becoming more commonplace. If the volumes do not support an interface, a lab portal is an option to support ordering and downloading of results.

Interfacing systems can include both ordering and resulting. Interfaced orders have the added benefit of improving operational efficiency. The lab no longer relies upon handwritten orders, allowing for more efficiency in accessioning. In addition, such systems will potentially reduce upfront accessioning errors and possibly improve billing. All of this comes with added expense, both upfront capital investment and maintenance or subscription costs.

The main purpose of the outreach laboratory is to grow volume from external clients. The key component of the front office is the sales team. Smaller programs may split an employee's role to be dedicated in part to working with a variety of clients. Other programs may hire dedicated sales teams to manage specific service lines, such as physician sales, hospital sales, etc. Regardless of the setting, the role is generally the same: they interact with potential clients, attempting to convince them that their outreach program provides more value, fulfilling clients' unmet needs. Of course, the ultimate goal is to acquire new clients and testing volumes in order to generate revenue.

Within many industries, sale functionality and account management may be separated into two different teams. Within laboratory outreach programs, it is common for individuals to have a dual role in both sales and account management. They acquire new clients and subsequently manage the accounts over time. In this setting, their bandwidth to sell and acquire additional accounts decreases as they manage more accounts over time. This indirect relationship can negatively impact the financial growth rate of the outreach program and should be managed accordingly. Investment in client relationship management (CRM) software is often a consideration. This allows the outreach program and its various teams to collect pertinent functional data to drive strategic growth. The associated metrics are critical for interpreting financial trends, strategizing market approaches, and managing the service. Depending upon the outreach program, additional front office functions may be considered, such as marketing. The degree and extent will vary depending upon the size of the program. These are strategic business tools, and the return on investment should be carefully considered and tracked.

To be successful, sales personnel require varied support that is typically provided by the back office. This functionality is quite varied and includes finance, human resources (HR), IT, office support, technical data support, client services, and more. For many programs, creating a stand-alone back office is outside their scope. Some of the functionality should be created and managed within the outreach program as it grows, but other areas remain part of the hospital or healthcare system. Human resources is a good example. There is no need for outreach programs to develop their own HR department. It is more cost effective to leverage the institution's HR department. This may hold true for other departments, such as finance, revenue cycle management, and IT, depending upon the size and scope of the outreach program. In this setting, robust communications and cross stakeholder management of services are required to ensure adequate function of different services. This is particularly true for the outreach service, whose structure and purpose are different from those of the typical lab.

Determining which investments and resources are required to compete and grow volume is complicated, reflecting the scope of the outreach program. These investments are strategic decisions reflecting the cost to compete and capture business within specific markets. Therefore, one size does not fit all. Understanding the potential return on investment and tracking the return over time to manage the service are imperative. These different considerations incrementally increase the cost to perform outreach lab service, impacting the financial performance and possibly solvency of an outreach program. If an outreach program attempts to compete within a competitively priced marketplace, understanding these costs is even more critical.

Levels of Decision Making in Outreach Operations

Menu: To Test or Not To Test

Ideally, of course, a hospital clinical laboratory's decision about whether to offer a given test on its test menu should be driven by objective evidence of clinical need, by perceived patient benefit, and ultimately by measures of patient outcome associated with the test's use. In this

本书版权归John Wiley & Sons Inc.所有

context, it is largely a medical-technical decision that depends upon a consideration of the test's potential "contribution to mission" for the institution and is the responsibility of the laboratory director. Within the hospital, the laboratory director is typically also responsible for participating in the management of laboratory test utilization, which is especially important under managed-care arrangements and increasingly necessary for federal compliance. If offering a given test will result in increased levels of inappropriate utilization (e.g., if its published diagnostic performance is such that a great many false positives or false negatives leading to unnecessary workups are associated with its use), then the laboratory director may face the challenge of educating the medical staff about this by opposing the test's inclusion in the laboratory's menu.

In outreach, while most of these underlying ethical and regulatory considerations are the same, the economic aspects of this decision making can be somewhat different. It will be useful to compare and contrast the situations in each setting with respect to the important questions associated with test menu decisions.

First, is the test reimbursed? The decision about including a test in the laboratory's menu will have this as a fundamental consideration, whether the test is offered for hospital inpatients, outpatients, or outreach clients (nonpatients). But whether and how any given test is paid for, and the circumstances under which it may make sense to include an under- or unreimbursed test in the menu, will definitely differ. The subject of clinical laboratory reimbursement is an extremely complex one, requiring knowledge of the detailed history of federal and state healthcare reimbursement programs, third-party payors, and managed care.

In dealing with this issue, first, it is essential to know the difference between reimbursements and charges. In the context of outpatient fee-for-service within the hospital, the charge for a given test is the amount associated with it in the institution's charge description master (CDM). It represents the amount the hospital theoretically bills all fee-for-service payors for the test. It is important to realize that this is a purely nominal figure, however, and the "revenue stream" that results from such fee-for-service billings, called gross revenue or gross billed revenue, does not actually exist as such in today's world, except in certain increasingly unusual circumstances. Note, however, that gross revenue is typically the only laboratory revenue data available to laboratory management on in-hospital work.

What the hospital actually gets paid is either directly determined by federal or state government policy (in the case of Medicare/Medicaid) or strongly influenced by it (in the case of other third-party payors). The test's rate of reimbursement by these payors is driven by its billing code, e.g., the Current Procedural Terminology (CPT) code assigned by the American Medical Association and updated annually (https://www.ama-assn.org/practice-management/cpt). To know whether a given test is reimbursed, therefore, the first question to be answered is, does it have a CPT code assigned at this time? (There is usually a very long lag between application for and assignment of new CPT codes.) If the answer is no, financing the test through the usual channels will be difficult. New tests and laboratory-developed (or "home-brew") tests that are truly novel (as opposed to merely novel methods for accepted analytes) are often assigned to a category of "research use only" or "not for *in vitro* diagnostic use" until they have been approved for diagnostic use by the U.S. Food and Drug Administration under its 510(k) or premarket approval processes. Medicare/Medicaid does not reimburse this test category until specific CPT codes are assigned. Attempting to bill under a general "miscellaneous"-type billing code is virtually guaranteed to be unsuccessful.

In contrast to this, in fee-for-service situations the outreach laboratory will bill not based on a CDM but rather from a fee schedule. The price at which the test is sold to a client will usually represent a value that is negotiated to include a discount off of the fee schedule list price. These negotiations may often include loss leaders, i.e., tests sold to the client at or below cost to meet an overall service need or provide "one-stop shopping." Note, however, that predatory pricing, involving discount of the full fee schedule below the lab's cost, is usually done for the purpose of excluding competition. Clearly, such pricing cannot be sustained over the long run, and it is only the larger laboratories, i.e., the "deeper pockets," that can hold out long enough to drive smaller competitors out of specific markets.

Outreach laboratory billing will vary based upon the types of clients it serves. The two most common client types can be categorized as hospitals and physician offices. In addition, a category comprising nursing homes, skilled facilities, and the like, is not uncommon. This service line is often difficult to manage given competitive market pricing, increased preanalytic costs, and thin margins. Last, some programs have other service lines reflecting their areas of expertise, such as an anatomic pathology service focusing on consultation work or primary work. From a billing perspective, the outreach program may face direct client billing, patient billing, commercial insurance billing, or Centers for Medicare and Medicaid Services (CMS) billing. Some service lines, like hospital clients, tend to bill clients directly only. Other clients, such as physician offices, often prefer that the patient's insurance or CMS be billed directly. Last, some service lines, like anatomic pathology, may have a mixture of billing types, even within the same client. Outreach leadership must decide their facility's tolerance in accepting the different types of billing. In addition, the outreach program will require the

本书版权归John Wiley & Sons Inc.所有

support of a revenue cycle management team with sufficient billing processes to manage the claims and billing. In addition, questions on CPT coding and efficiency of claim management will impact the success of the outreach program.

The amount that either the hospital or the outreach program actually gets paid for a given test (called the net revenue or net collected revenue) is equal to the billed amount minus allowances, controllable losses and inefficiencies, and bad debt. Allowances include cost-based reimbursements, reductions in payments based on discounted charges, and charity care. Bad debt is other unpaid and uncollected billings. The reimbursement rate depends upon the type of financing in place for the patient for whom the test was ordered (known in the aggregate as the provider's payor mix).

If the service is being provided under a managed-care arrangement governed by capitation, then there is no billing at all for the test; its cost is simply reimbursed as part of the managed-care organization's *per capita* payments to the hospital or laboratory for its members' care (e.g., a prenegotiated per-member per-month [PMPM] rate). Any positive margin earned by the hospital or laboratory under these circumstances is strictly a function of the degree to which it can minimize both unit cost and utilization of testing. Negotiating managed-care contracts under capitation is a very specialized subject and is beyond the scope of this chapter.

As mentioned above, pricing of outreach testing must ultimately be based on the unit cost plus a markup representing profit margin. It must also, of course, reflect what the market will bear; i.e., it must be competitive with the pricing of the other lab providers, including national reference laboratories, operating in the area. Therefore, it can be crucial that the costing of the test reflect a true sense of the marginal or incremental net cost of its production, given the hospital's sunk costs and excess capacity. Table 38.2 presents the levels of financial decision making involved when deciding whether to offer a test. These concepts are illustrated in some of the material below.

Table 38.2 Levels of financial decision making in lab outreach

Question	Answer	Resulting action
Offer test?	Yes	Proceed to next question
	No	Monitor potential need
Perform test in house?	Yes	Proceed to next question
	No	Make send-out arrangements
Does test require new equipment?	Yes	Proceed to next question
	No	Validate, set up assay
Purchase new equipment?	Yes/no	Analyze alternatives financially

Operation: To Perform In-House or Send Out

Given a decision to offer a test as part of the laboratory's menu, the next decision is whether to set up the new test in-house or to send it out to a reference lab. In addition to the logistical considerations of test turnaround time and availability, an essential financial consideration in this decision is the concept of the laboratory's net contribution margin (for in-hospital work) or net profit (for true outreach) for a given test. This is defined as the total net revenue generated by the test minus the total unit cost (both direct and laboratory-related indirect costs) for which the laboratory is responsible.

A sample problem adapted from one presented in reference 5 should make this clear, while also showing how some of the different cost-related concepts discussed above are used in a typical make-or-buy decision: Suppose a laboratory offers a test on its menu and charges $10.00 per billable result for it. Suppose further that a calculated, fully loaded total cost per billable for this test is $13.00, which includes all test-specific direct costs at $5.00, all laboratory-specific indirect costs at $4.25, and all hospital-wide allocated indirect costs at $3.75. Calculating the test's profit or contribution then gives $10.00 – $13.00=–$3.00, a loss on each test performed. If the laboratory performs 1,000 of these tests annually, the extended loss becomes $3,000 per year. If the test, offered at $10.00 per billable, were purchased by the laboratory as a send-out from a commercial laboratory at $8.00 per billable instead of being produced in-house, the loss would apparently turn to a profit (handling fee) of $2.00 per billable. Is this what should be done?

The reasoning here needs to be scrutinized by concentrating on exactly which costs of performing this test are relevant in this decision-making process. The test-specific direct costs of $5.00 per billable include $3.52 for direct labor, $0.48 for direct reagents and disposables, and $1.00 of other direct costs. These are out-of-pocket cost savings that will be realized by no longer performing the test on site. The labor cost may be considered fixed in this case, because the technologists are likely to remain on staff. For purposes of this example, assume labor to be a truly variable cost savings. The appropriate analysis, then, would be as shown in Table 38.3. The $8.00 purchase price, if the test is sent out, results in a net increase in out-of-pocket cost of $3.00 per billable above the savings in direct costs of $5.00. Since the indirect costs

Table 38.3 Factors in the decision to make or buy a test

Factor	Make (continue in-house testing)	Buy (from reference lab)
Charge	$10.00	$10.00
Direct costs	$5.00	$8.00
Indirect costs	Not relevant	Not relevant
Contribution	$5.00	$2.00

本书版权归John Wiley & Sons Inc.所有

incurred by the laboratory remain in effect, regardless of this decision, arguably they should not be considered relevant. Therefore, if the test is continued in-house, its net profit is greater. If the labor component is treated as a fixed cost (the technologist would remain on staff), then labor, like the indirect costs, would no longer be relevant, and the argument for continuing to do this test in-house would become even stronger. The methodology underlying this discussion is called break-even analysis. If the revenue and cost associated with a procedure like this one (or an instrument or a methodology) are both plotted on a graph of test volume (x) versus dollars (y), they will cross at a point representing a net contribution of zero, i.e., the point at which revenue equals cost, called the crossover or break-even point.

Assume for the moment that a hypothetical laboratory is currently operating at the break-even point determined by the calculations above. What about next year? What happens if volume, cost, and/or revenue increases or decreases? The method most often used for exploration of such what-if scenarios is sensitivity analysis. This technique uses data provided from the break-even analysis and provides potential insight into the effects of changes in costs, revenues, volumes, and/or net income. Basically, the calculations are repeated with substitution of the hypothetical change in one variable at a time. For example, consider whether the above decision would be different with any of the following changes in the conditions. Suppose there was a 20% increase in test volume, or a price increase that produces a 20% increase in revenue, assuming no bad debts or allowances, or a 20% reduction in variable labor expense for the same test volume. Virtually any future situation may be simulated with the use of current data. Although sensitivity analysis has the virtue of relative simplicity, it should be applied with some caution. It assumes that all costs are either variable or fixed (i.e., no mixed costs), that variable costs are a linear function of (directly proportional to) volume, and that a relevant range exists for all levels of activity. Though these simplifications make the analysis possible, they may influence interpretation of analytical results, such that an appropriate degree of "taking it with a grain of salt" is always in order.

Note that federal tax and regulatory considerations, the so-called shell laboratory provisions, dictate an effective upper limit for the portion of a laboratory's volume that can be sent out to another laboratory. Basically, a laboratory that is sending out more than 30% of its work to be performed elsewhere is regarded as not actually being in the laboratory business under federal fraud and abuse regulations.

Capital: Whether To Acquire New Equipment

Given a decision to "make," i.e., produce test results in-house, the next decisions involve the use or acquisition of any capital equipment that may be involved. This aspect of planning, capital budgeting, may be interdependent in the outreach laboratory with both operational budgeting and strategic planning. It may include allocations for major investments in buildings as well as equipment. In accounting terms, a capital item is commonly defined as a fixed asset that is expected to provide service (i.e., have a useful life) of more than one year. Within this broad definition, some important distinctions among concepts should be kept in mind.

Repair and maintenance of capital items, for example, should be differentiated from capital improvements. Maintenance and repair provide ongoing upkeep of the investment and are most appropriately treated as operating expenses. Since capital improvements are just that—that is, they make the items better than when purchased—they are most appropriately treated as capital expenses. Replacing an entire fixed asset should be regarded as a capital expenditure whereas replacing a component part is best treated as an operating expense.

Leasing arrangements differ in whether they define a given expense as a capital or an operating line item. Relatively inexpensive new items with useful lives of greater than 1 year are often initially classified as capital, but their replacements are treated as operating expenses from then on (e.g., certain furniture items and items costing $500 or less).

The budgeting period is very important for capital budgeting. In outreach work, review of capital needs should occur at least annually. Long-term planning, while always desirable, may often not be possible in today's dynamic marketplace. The longer the time horizon used, the more likely it is that the predictions involved will be inaccurate, so this process must always be approached flexibly.

Capital budgets typically contain separate categories for minor and major items. Minor capital consists of relatively low-cost items, perhaps under $2,500, requiring less in the way of analysis. This may just be an outline of the costs, along with an indication of whether the item is a replacement, new item, renovation, improvement, or regulatory requirement, along with a brief budgetary justification. These items may just be prioritized numerically or may be classified into the following categories: (i) needed to continue present service, (ii) needed to support recent volume growth, (iii) providing opportunity for cost savings or profit at the existing volume, (iv) providing opportunity for improvement in quality or service levels, and (v) providing opportunity to implement new programs or initiatives.

Major capital items, e.g., items over $2,500 (or a similar figure), may be split up into annual purchase requests over a longer (3- to 5-year) period and generally require more in the way of analysis. Supporting documentation needs to be more detailed and specific, often involving statements or descriptions of (i) general purpose, (ii) importance, (iii)

本书版权归John Wiley & Sons Inc.所有

projected client demand and utilization, (iv) availability of alternatives, (v) estimated useful life, (vi) estimated total acquisition cost, (vii) estimated associated yearly cash outflows, and (viii) estimated yearly cash inflows or savings.

It may be difficult to make these last two projections, but such data on expected cash flows are crucial to the analytic techniques used in evaluating capital alternatives. In performing these projections, consider only incremental amounts. Be concerned only with marginal or additional cash outflows and inflows that will occur as the direct result of the new project above and beyond the current baseline. Count only *cash* inflows and outflows, bearing in mind that accounting statements of revenue and expense that are maintained on any basis other than a cash basis are likely to yield inaccurate estimates of the actual cash either generated or spent.

In the clinical laboratory business, capital items are vital to financial capability and future viability. An attempt must therefore be made to ensure a reasonable return on the investment represented by each capital item. Return-on-investment (ROI) calculations (discussed in some detail in Appendix 38.2) need to start with an estimation of this return percentage, referred to as the required rate of return (or discount rate). In the example adapted from reference 4 and given in the appendix, a 10% rate is used. The actual required rate of return on a given project may be based on any of a number of factors that may include (i) the cost of borrowing new funds (i.e., the interest rate at which the laboratory can borrow money); (ii) the return realized on investments of laboratory profits in short-term liquid investment instruments, such as money markets, government securities, or certificates of deposit; (iii) in a for-profit environment, the ROI expected by stockholders; and/or (iv) a "fudge factor" accounting for possible misestimates in the calculation or the relative riskiness of the project.

Financing Capital: To Lease or Buy Equipment

Given a decision to acquire a new piece of equipment, the next decisions revolve around determining the least costly financing alternative. The lease-or-buy decision is an application of present-value analysis, as described in Appendix 38.3. Following generally accepted accounting principles (GAAPs), there are two types of leases, known as cancelable and noncancelable leases. In cancelable leases, if the laboratory can cancel the lease and cease making payments whenever it chooses without penalty, the lease is called an operating lease and is treated as an operating expense. If, for the term of the lease, it cannot be canceled and there is an option to purchase the equipment, then the lease is called a capital lease, is viewed as a form of capital borrowing for a purchase, and is accounted for as a capital acquisition within the capital budget.

Financing alternatives typically are (i) to purchase the item from the laboratory's internal funds, (ii) to borrow external funds for its purchase, or (iii) to lease the equipment. The costs associated with each of these approaches can be analyzed side by side using the present-value methodology as described in Appendix 38.3.

Financial Considerations in Outreach

Role of Metrics-Based Decision Making

The financial data associated with the outreach service are critical to guide strategy and support business decisions. Developing financial data can be problematic, particularly within new outreach programs in well-established laboratories. Outreach services are initially developed by leveraging unused capacity. Although their volumes are derived from external clients, they are comingled with institutional volumes during testing and may represent a small fraction of total volumes. If the system is not appropriately set up, it can be difficult to identify external clients from institutional volumes. Small volumes, particularly for nascent programs, make it difficult to invest resources to build the system to differentiate client volumes within the laboratory information system. In addition, the financial software needs to be to set up to track and analyze the outreach program independent from the institutional volumes.

The comingling of data makes it quite difficult to evaluate outreach laboratory financial performance. This is critical on multiple levels and becomes a growing concern as the service volume increases. The financial data are an important consideration in understanding local market trends and where to deploy the sales force. When evaluating strategy in the short and long term, financial data play a critical role in deciding how and where to grow. The data are critical when evaluating sales data and performance, ensuring efficacy and appropriate resource utilization by the front office (e.g., client-facing teams). In order for the outreach to manage its front office teams and account management performance, it requires sufficient financial data. The list continues even further. The outreach program is a business that relies on financial data to drive decision across its operations.

Establishing outreach data, financial and otherwise, independent from the core lab business is an important step to manage the service. This will result in tremendous amounts of interrelated data, including laboratory, financial, and sales data. The amount of analysis and metrics that can be deployed is extensive, possibly overwhelming the service. Metrics and analysis should be appropriately deployed to answer specific questions and manage specific workflows. As the service grows, more complex analyses may be developed to meet functional needs. From a high level, tracking realization rate as well as accounts receivable is a useful starting point to oversee revenue that simultaneously provides insight into system workflow at different levels.

本书版权归John Wiley & Sons Inc.所有

Realization Rate

Within the healthcare system setting, some laboratories see revenue as the gross figure. This is a misleading figure not reflecting actual collections. There is a sizable difference between the hospital fee schedule and third-party contractually adjusted rates. In addition, CMS rates are much lower than the list price of testing. Ultimately, gross revenue markedly overrepresents realized revenue. This is further compounded by the disassociation between cost and revenue within the hospital lab. Within the non–for-profit setting, the budget is typically not tied to revenue generation. Rather, it is created with a focus on cost containment regardless of revenue or EBITDA (earnings before interest, taxes, depreciation, and amortization)/EBIDA performance. Some hospital laboratories will develop high-level profit-and-loss statements with some visibility on collections through revenue cycle management. However, robust visibility on cash flow is unusual in the setting of the clinical laboratory. Being able to manage billing, reduce controllable losses, and maximize revenues is critical.

The realization rate reflects the rate of revenue collected in comparison to expected value. A simple way to calculate it is to divide net revenue by gross revenue. This may work if we define the values as follows: net revenue is the revenue collected over time through the billing process and mechanisms; gross revenue is the volume of tests multiplied by the fee schedule.

Depending upon how the system is established, different types of billing scenarios will have different realizations rates. If you load a client-specific fee schedule for direct billing, the theoretical realization rate should be 100% for those clients. If the entire service line is composed of clients with direct billing, the theoretical realization rate if every client paid every invoice would approach 100%. Although the realization rate can be used in the setting of direct client billing, following accounts receivable (AR) and the invoicing cycle is often a more robust tool to manage direct billing.

The realization rate associated with third-party billing will vary depending upon contractual relationships and negotiated rates. Larger institutions often rely on a managed network service department that oversees relationships with third-party insurers. Regardless of the mechanism, the outreach laboratory will rely on these contracts. The negotiated rates and payment terms will impact the outreach service's finances. Overall, the realization rate for third-party billing will be higher than for CMS. Although the negotiated contractual adjustments set the overall price structure, the realization rate will also be impacted by various other factors. These will include client setting, mixture of testing, billing efficiency, controllable losses, and more. The payment for testing in regard to CMS is typically lower, resulting in lower realization rates within the outreach laboratory. As before, other variables will impact the actualized realization rate, including efficiency of billing, controllable losses, mix of tests, client type, and more.

On a macro level, a realization rate is typically calculated by dividing net revenue by the gross revenue. For a third-party insurer or CMS reimbursement, the net revenue reflects substantial adjustment from the gross revenue secondary to contractual agreement. These contractually agreed-upon modifications account for the largest shift in test revenue realization and are expected. Nonetheless, this represents a sizable shift in revenue, highlighting the importance of contractual negations with third-party insurers.

Multiple factors in addition to contractual adjustments impact the realization rate. Denials are common occurrences in both insurance and CMS billing. Revenue cycle management (RCM) will work with external parties to resolve denials, but some charges will remain denied. This will result in decreased net revenue, further depressing the realization rate. The RCM team will have to actively analyze the data to understand the scope of controllable losses and understand trends. There are many points within claim the process that can result in denial, starting from the client, to accessioning, and to billing, and including the insurer. Issues like medical necessity and insufficient claim information can impact denial rates. The RCM team has to work with the outreach program to minimize causes and denial rates. This will include a review of client causes and working with clients to address issues with their process, resulting in loss revenue and decreased realization rates. Issues with patient registration or specimen accessioning may impact billing. Sometimes, the information system and its build will have problems shifting realization rates. This metric provides insight into how various workflows impact revenue generation. However, defining appropriate realization rates for specific outreach laboratories or service lines can be difficult.

A theoretical maximum realization rate can be calculated in various settings. For CMS and third-party billing, this would be calculated based upon CMS or contractually agreed-upon adjustments to the price per test. If the figure is divided by the fee schedule, the quotient is the realization rate per test. Although interesting in specific circumstances, this may not be entirely useful in managing the broader service. Volume impacts the overall realization and is an important consideration in managing the service.

An aggregate realization rate factoring in volumes can be created as follows. The numerator would reflect the sum of each test after each test's volume is multiplied by the contractually adjusted fee or CMS fee, depending upon which realization rate you are calculating. The denominator would reflect the sum of each test after each test's volume was multiplied by the fee schedule.

本书版权归John Wiley & Sons Inc.所有

Numerator: (test 1 total volume × 3rd-party adjusted fee)
+ (test 2 total volume × 3rd-party adjusted fee)
+ (test 3…)

Denominator: (test 1 total volume × fee schedule)
+ (test 2 total volume × fee schedule)
+ (test 3…)

This value provides insight into the expected rate to be received from outreach work. However, it is not a metric but a benchmark or a theoretical maximum if everything is collected that could be collected. This exercise can be performed in different settings as appropriate to manage the service. It can be broken down into individual tests by volume to evaluate the performance of a specific test if needed. Service lines can calculate their specific rates to use as a benchmark to evaluate their performance. Different third-party insurance providers can be evaluated to determine their performance for strategic decision making. Individual clients can be evaluated as well. For many programs, this will reflect substantial work and should be used to answer specific questions or manage certain circumstances.

In the setting of CMS and third-party insurance companies, the process of billing is involved and complicated. In addition to submitting claims, some claims will require follow-up and others will be denied. Those that are denied or have issues will have to be managed or worked up for possible payments. Between denials, controllable losses, clients who fail to pay their bill and more, the actualized realization rate will be lower than this theoretical maximum. From a practical perspective, the outreach laboratory cannot expect the realization rate to consistently equal the theoretical rate. Some degree of deviation is to be expected. Outreach management, revenue cycle management, and other stakeholders have to work together to continuously identify controllable losses and push for solutions to close and maintain the smallest gap.

Direct Client Billing and Accounts Receivable

Unlike CMS and third-party billing, direct client billing is relatively less involved. After completion of work, an invoice is generated and submitted to a client for payment. Those with contracts in place typically have payment terms, often 60 days from the time of invoice receipt. For those without a contract, the invoice typically details payment terms and provides a lower level of legal protection.

Although the process is simpler, it requires oversight nonetheless. If the outreach laboratory does not manage direct billing well, clients may become accustomed to the lack of oversight and not take the outreach program seriously. Insufficient attention entails the risk of ballooning past-due accounts, resulting in excessive bad debt and excessive write-offs. This represents financial loss and work being performed free of charge.

Managing AR is a joint effort between various internal stakeholders. The finance team is needed to track AR reports and ensure sufficient communication with the outreach laboratory. Sufficient visibility on <30-day, 30- to 60-day, 60- to 90-day, 90- to 120-day, and >120-day AR balances is useful for determining whether clients are paying and paying on time. These time points are not fixed but are the typical time frames used. Multiple sophisticated metrics can be employed to support AR payment cycles. However, review of client and aggregate reports and simple calculations can go a long way in supporting and managing the service.

Based upon the data, a workflow should be established to communicate to clients when their account becomes past due. Suggested time points include 60 days, 90 days, and 120 days past due, but these can be modified to meet an outreach laboratory's needs. Client communication and management will impact payment rates. Passive automated mechanisms are efficient but should be monitored for efficacy. They lack an attentive touch and may be disregarded by clients. However, direct communication expends higher efforts, reflected in higher labor force costs. These are management decisions based upon specific outreach considerations.

Despite the team's best efforts, some clients will not pay. At some point, the outreach laboratory will consider shifting accounts into bad debt and onto collections. When accounts are submitted for collections, often a third-party collections agency is used. The rate of collections is much lower, and the outreach lab should expect a fraction collected on the dollar. One of the consequences of moving a client to bad debt is to remove the outstanding balance from your client's account within your financial reporting. The account will no longer be seen within the AR report and the amount will fall off the list of >120-day outstanding debts. The amounts can be tracked separately as a "bad debt" list, but they will no longer impact your routine work and reporting.

When a client's account is shifted into bad debt, the outreach lab assumes some key failures. Before making this transition, there should have been sufficient attempts at communicating with the client. Sometimes communication methods fail. Therefore, it is suggested that the outreach laboratory verify that the client is receiving such notices. Other times, the client may have mitigating circumstances. In other words, shifting a client to bad debt should be done once the outreach lab has verified that they have diligently communicated and that the client has failed to pay without any mitigating circumstances.

At this stage, the outreach laboratory has an important decision. If the client's failure warrants shifting that account to bad debt, it should be sufficient to terminate that

本书版权归John Wiley & Sons Inc.所有

individual as a client. If the client has a contract, such contracts typically include clauses defining client breach of contract, allowing the outreach laboratory to terminate in such circumstances. Nonetheless, this can be a difficult decision for outreach laboratories to make.

The loss of a client is a loss of volume and a perceived loss of revenue. For some, the thought of terminating a client after all the work of acquisition and on-boarding is difficult. In actuality, work is being performed with no payment. From a cash flow perspective, the client's failure to pay results in a financial loss to the laboratory. By terminating the client, there is reduction of losses, improving the overall financial health of the outreach laboratory. There may be circumstances in which a client is shifted into bad debt but is not terminated as a client. This occurs in specific scenarios that leadership should consider carefully along with the impact on the service.

SUMMARY

Outreach can represent an alternative path in the development of a hospital laboratory, but it is one in which price competition becomes a basic reality and market share becomes a critical measure of success. The outreach laboratory, to provide its customers with the benefits of one-stop shopping, must compete on quality and service, and these are critical success factors that require investment. It may also, if it is large enough, have the opportunity to compete on technological innovation, but in reality this applies to relatively few hospital-based startup ventures. Mainly, it will have to compete on price, which means that, of necessity, it must produce as much as or more than the competition with the same or fewer material and human resource inputs per unit of service. It also means that the cost of new sales, in terms of the cost of marketing, sales activity, distribution, client service, and quality enhancements and/or technology improvements, must be managed as actively as are the costs of daily production. In all of this, familiarity with the basic types and interrelationships of costs is crucial. Ultimately, outreach is business oriented, relying on financial data and metrics to help guide and manage volume and revenue growth.

KEY POINTS

- An understanding of the nature and analysis of cost behavior has fundamental significance for decision making in outreach laboratory management.
- A large proportion of the typical hospital laboratory's costs are fixed, and this can create an opportunity for outreach when properly viewed as such.
- Key decisions that are financially driven include pricing and test menu decisions, make-or-buy decisions, and decisions about the financing and acquisition of equipment.
- Developing financial data and metrics is critical to managing the outreach service and ensuring financial growth.

GLOSSARY

Accounts payable A buyer's obligations or liabilities that usually arise from normal operations of a business. They are neither backed up by a negotiable instrument nor considered overdue. Contract obligations owed by individuals or the business on an open account.

Accounts receivable Balances due from debtors on current accounts.

Allowances Amounts to be subtracted from gross billings (along with bad debt) in the calculation of net revenue, including contractual and cost-based reimbursements, reductions in payments based on discounted charges, and charity care.

Assets All money, property, or valuables that are owned by an individual or organization. Assets may be used in whole or in part to pay off liabilities (debts).

Average rate of return (ARR) The average dollar return on a project divided by the average dollar investment it represents, usually calculated on an annual basis.

Bad debt Billings that are unpaid and uncollected and/or uncollectible.

Billing Presenting a statement of charges to another healthcare provider, such as a hospital or physician office (account bill or client bill), or to a patient (patient bill).

Billing code Standardized designation for medical procedures (such as laboratory tests) that are billable under federal government reimbursement rules, e.g., the Current Procedural Terminology (CPT) code assigned by the American Medical Association and updated annually.

Book costs Outstanding liabilities counted against the assets of a business as shown on its account books and reflecting allocations of past outlays to the current period.

Bottom-up microcosting Estimating the unit cost of a laboratory test by summing the estimated unit costs of each of the input components (materials, labor, etc.) for a single performance of that test (also called job order costing).

Break-even or crossover point The point in the life span of a business or project at which the revenue it generates equals its cost and thus represents a net contribution margin or profit of zero.

Capital item A fixed asset that is expected to provide service (i.e., have a useful life) of more than 1 year.

Capital lease A lease that cannot be canceled during its term and that typically includes an option to purchase. It is accounted as a form of capital borrowing for a purchase and is accounted for as a capital acquisition within the capital budget.

本书版权归John Wiley & Sons Inc.所有

Cash flow The patterns of receipts and expenditures of a company (or other entity) resulting in the availability or nonavailability of cash.

Charge In the context of outpatient fee-for-service within the hospital, the charge for a given test is the amount associated with it in the institution's charge description master (CDM), representing the amount the hospital theoretically bills all fee-for-service payors for the test.

Controllable costs Fixed or variable costs that can be influenced by a specific individual's decision making

Cost per billable result Unit cost of production of all the reportable results that are included in a unit of service, such as a test panel or battery that is made up of multiple individual analyte results but billed as a group.

Cost per reportable result Unit cost of production for all the items necessary to report a test result, including the individual analyte test result itself and all the quality control, calibrator, waste, and repeat results that are necessary to be able to report it.

Cost per test (or cost per result) Unit cost of production of a single individual analyte test result, representing both fixed and variable direct costs as well as allocations of certain indirect costs most closely associated with production: reagents, disposable supplies, equipment, and labor.

Depreciation Estimated allowance made in accounting for the decrease in value of a fixed asset through wear, deterioration, or obsolescence during its useful life; may be calculated by different standard methods.

Differential or incremental costs The change in future fixed and/or variable costs projected to result from changes in production methods, costs of inputs, or other events or specific courses of action.

Direct costs All costs that are incurred directly as a result of producing test results, e.g., technical, supervisory, and clerical wages; overtime; on-call payments; and chemicals and supplies specifically expended to perform the test.

Economy of scale Positive relationship between increased volume and decreased unit cost of production.

Fee schedule Listing of the prices charged for tests by an outreach laboratory in fee-for-service situations, i.e., in billing individuals who are not patients of the laboratory or its parent institution or in billing clients representing nonpatients.

Fixed assets The items of physical property (equipment, buildings, and/or land) owned by a business or other entity; also known as tangible or nonliquid assets.

Fixed costs Laboratory costs that remain unchanged for a given period of time, despite fluctuations in test volume, e.g., supervisory and custodial wages and benefits required regardless of volume, building maintenance and utilities, and depreciation.

"Fraud and abuse" provisions Portions of the Medicare and Medicaid regulations pertaining to definitions of prohibited laboratory business practices, such as physician self-referral and other forms of inducement and conflict of interest.

Future costs Anticipatable costs that potentially can be affected by current budget and capital-acquisition decisions and thus represent the most appropriate focus of planning.

Generally accepted accounting principles (GAAPs) A widely recognized set of standard accounting procedures and definitions.

Gross revenue or gross billed revenue The amount of gross income that would theoretically result if a hospital or laboratory could bill and collect all its charges from all its payors.

Historical costs Costs incurred by a business in the form of payments that are accounted for and recorded at the time of actual cash outlay (also known as sunk costs).

Imputed costs Costs incurred by a business in any form that do not involve actual outlay of cash, such as opportunity costs, depreciation, etc., which are not explicitly listed in accounting records but must be derived by calculation.

Indirect costs (overhead) All general laboratory costs not easily or directly traceable to the production of individual test results but included in total laboratory operating expenses, e.g., depreciation; building and equipment maintenance; insurance; utilities; housekeeping; and costs associated with purchasing and billing services, sales, marketing, and development.

Inflation Effective relative increase in the amount of money in circulation, resulting in a fall in its value and a rise in prices over time.

Job order costing *See* Bottom-up microcosting.

Lease A written agreement or contract by which one party (the lessor) gives to another (the lessee) the use and possession of property for a specified time (the term) and for fixed payments.

List price The price of a test listed in a laboratory's fee schedule and representing the nominal price charged to its fee-for-service clients (nonpatients and clients representing nonpatients). The actual price is typically negotiated to include a discount off the fee schedule list price.

Loss leader A test sold to a client at a price discounted below cost in order to meet an overall service need or provide "one-stop shopping." Note that it is not legal to loss lead entire accounts, but only individual tests within an account. *See also* Predatory pricing and "Fraud and abuse" provisions.

Marginal cost The incremental cost of adding one additional unit of test production.

Microcosting Calculating the unit costs of test production to account for each and every category of expense involved at the laboratory's current test volume; performed in either a bottom-up or top-down fashion.

Mixed costs Costs that are somewhat, though not totally, dependent on volume, i.e., are difficult to classify definitively as either fixed or variable, e.g., clerical staff.

Net contribution margin For all hospital inpatient and outpatient testing, the total net test revenue generated by the laboratory, minus the total cost of test production (both direct and laboratory-related indirect) for which the laboratory is responsible, constitutes its contribution to the hospital's bottom line.

本书版权归John Wiley & Sons Inc.所有

Net present value (NPV) The present value of all the cash flows created by a project minus the dollar amount of the initial investment in it (also known as the time value of money associated with the investment).

Net profit For all true outreach nonpatient testing, the total net revenue generated by the laboratory, minus the total cost of test production (direct and indirect) for which the laboratory is responsible, constitutes the laboratory's profit.

Net revenue or net collected revenue The amount either the hospital or the outreach program actually gets paid for a given test, equal to the billed amount minus allowances and bad debt.

Noncontrollable costs Costs outside the scope of a specific individual's control.

Operating lease A lease that can be canceled during its term and that typically does not include an option to purchase. It is accounted as a form of operating expense.

Opportunity costs Imputed costs representing missed opportunity, i.e., the potential financial gain that is missed when a more profitable use of resources (materials, labor, facilities, or capital) is rejected or abandoned in favor of a less profitable one. Opportunity costs are lost revenue, not expenditures, and they represent variable costs whose amounts depend on the alternatives under consideration. (They are related to the concepts of the time value of money or net present value, i.e., best use of funds among competing investments.)

Out-of-pocket costs Costs involving immediate expenditures, i.e., incurred as cash outlays occurring at or near the time of purchase; potentially important in capital budgeting.

Overhead *See* Indirect costs.

"P and L" (profit and loss) responsibility Individual financial accountability for a business or portion of a business implies that all of its costs are controllable, either directly or indirectly, by that individual.

Patient Individual receiving care (and laboratory testing) after being registered and seen in a hospital-affiliated clinic (outpatient), after being registered and admitted to the hospital (inpatient), or as a client of the laboratory's outreach business with no other connection to the hospital *per se*.

Payback period The period of time that a capital investment takes to be completely recovered from its resulting cash flows.

Payor mix The distribution of the different forms of healthcare financing in place among the population served by a healthcare provider, e.g., Medicare, Medicaid, private pay, managed care, uninsured, etc.

Period costs Costs that represent fixed outlays for the whole lab or the whole hospital per unit of time.

Per member per month (PMPM) rate For services provided under a managed-care arrangement, the managed-care organization's per capita payments to the hospital for its members' care. Under such arrangements, laboratory tests are most typically bundled; i.e., there is no separate billing for tests, which are regarded as being reimbursed as part of the overall capitated payment.

Predatory pricing Discount of the full fee schedule to a client below the laboratory's cost, if done for the purpose of excluding competition; this is unethical and illegal.

Present value (PV) or time value of money The dollar amount that, if it were invested now at a given rate of return, would accumulate to a given specified value at a specified time in the future.

Process costing A method of microcosting in which unit costs are estimated from aggregate expenses divided by units of service. Also referred to as top-down microcosting.

Relative value unit (RVU) Workload units accounted under any of several weighting systems devised and implemented by professional organizations to account for a labor component involving significant professional time spent on cognitive interpretative tasks in the production of certain test results, like surgical pathology reports, in order to equitably bill for them. The laboratory costs associated with these billables can be accounted as cost per RVU.

Return on investment (ROI) Calculation (involving a variety of different methods) of a specified payback amount (also known as the required rate of return or discount rate) on a given investment.

Sensitivity analysis A method for testing premises used in decision making, i.e., determining the sensitivity of conclusions derived from calculation to the ranges of numerical values chosen as inputs with substitution of the change in one variable at a time to determine their effects (also known as what-if calculations or best- and worst-case scenarios).

Service costs Costs that are incurred as tests are performed, representing variable costs plus those fixed costs that are most directly traceable to the testing, and related to the concept of cash flow.

"Shell lab" provisions Portion of federal fraud and abuse regulations dictating an effective upper limit for the portion of a laboratory's volume (30%) that can be sent out to another laboratory.

Straight-line depreciation Standard accounting method of calculating depreciation of fixed assets that involves equal weighting of time periods.

Sum of the years' digits (SYD) method Standard accounting method of calculating depreciation of fixed assets that involves unequal weighting of time periods.

Sunk costs *See* Historical costs.

Top-down microcosting *See* Process costing.

Unit costs Costs per unit of production or unit of service provided (test, reportable result, billable result, or RVU), accountable as total of fixed plus variable costs per unit.

Variable costs Direct or indirect costs that vary in direct proportion to test volume, e.g., technologist wages and benefits, reagents, glassware, disposable supplies, and forms.

本书版权归John Wiley & Sons Inc.所有

ACKNOWLEDGMENT

This chapter is an updated version of chapter 43, "Finance and Decision Making in Outreach," by Michael G. Bissell and Harry E. Pukay-Martin in the previous edition of this book.

REFERENCES

1. **American Medical Association**. 2010. *CPT 2010*. American Medical Association Press, Chicago, IL.

2. **Bennington JL**, **Westlake GE**, **Louvau GE**. 1974. *Financial Management of the Clinical Laboratory*. University Park Press, Baltimore, MD.

3. **Shuffstall RM**, **Hemmaplardh B**. 1979. *The Hospital Laboratory: Modern Concepts of Management, Operations, and Finance*. C.V. Mosby Co, St. Louis, MO.

4. **Snyder JR**, **Senhauser DA**. 1989. *Administration and Supervision in Laboratory Medicine*, 2nd ed. J.B. Lippincott, Philadelphia, PA.

5. **Travers EM**, **Delahunty DC**, **Hunter LL**, **McClatchey KD**, **Rudar JM**. 1998. *Basic Cost Accounting for Clinical Services. Approved Guideline GP11-A*. National Committee for Clinical Laboratory Standards, Wayne, PA.

6. **Ullmann JE**. 1976. *Theory and Problems of Quantitative Methods in Management. Schaum's Outline Series*. McGraw-Hill, New York, NY.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 38.1 Microcosting

LABOR

Below is an example of the calculations to determine real labor costs.

Salary spreadsheet	Potential hours
Sara Smith	
Base salary ($)	48,006.40
Salary per hour ($)	23.08
Fringe benefits (%)	32.2%
Salary per hour with benefits ($)	30.51

	Days	Hours
Starting amount		2,080
Vacation	20	160
Holidays	10	80
Sick leave	6	48
Available hours		1,792
Rate	0.86	
Available hours rate	35.42	
Production percentage	90%	
Production rate or real cost of labor	39.35	

Production Table	
Production percentage	**Nominal rate**
100%	35.42
90%	39.35
80%	44.27
70%	50.59
60%	59.03

TEST

See the next page for an example of microcosting a single test.

(continued)

本书版权归John Wiley & Sons Inc.所有

APPENDIX 38.1 Microcosting *(continued)*

Test: XYZ Test								IHC				
	ENTER# in one Case	ALL COSTS ARE COST PER SLIDE										
Patient slides	**1**											
Neg control slides	**1.00**											
Separate pos control slides	**0**											
		Number of slides					Enter #					
Item		1	2	3	4	12	15	Comment				
Fixed costs				Normal run								
Supplies	Dako High pH Antigen Retrieval Solution, code S2367	$8.84	$9.42	$6.28	$4.71	$1.57	$1.26	50 ml from a 10× concentrate (or 5 ml of actual products), used for 1–24 slides, 110 ml per order @ $414.48 per order or $18.84 per run				
	Fisher 30% H2O2, catalog H325-500	$1.64	$0.82	$0.55	$0.41	$0.14	$0.11	1 run requires 20 ml (1–24 samples), 500 ml per order @ $41.01, or $1.64 per run for 1–24, $3.28 for 25–48				
	Xylene	$5.39	$2.70	$1.80	$1.35	$0.45	$0.36	1 run requires 100 ml, 1 liter per order @ $53.92 or $5.40 per run				
	100% alcohol	$1.63	$0.82	$0.54	$0.41	$0.14	$0.11	1 run requires 100 ml, 1 liter per order @ $16.33 or $1.63 per run				
	95% alcohol	$1.59	$0.80	$0.53	$0.40	$0.13	$0.11	1 run requires 100 ml, 1 liter per order @ $15.9 or $1.59 per run				
	Richard Allan Hematoxylin, catalog 7211	$6.43	$3.21	$2.14	$1.61	$0.54	$0.43	1 run requires 50 ml, 1 liter per order @ $128.51 or $6.43 per run				
	Total cost per slide	$35.52	$17.76	$11.84	$8.88	$2.96	$2.37					
Labor	Technician time	$117.18	$58.59	$39.06	$29.30	$9.77	$7.81	2 h total (5 h w/machine time) 60% productivity @ $60.63/h				
	Total	$117.18	$58.59	$39.06	$29.30	$9.77	$7.81					
Total fixed costs		$152.70	$76.35	$50.90	$38.18	$12.73	$10.18					
Total cost per case		**$305.41**	**$152.70**	**$101.80**	**$76.35**	**$25.45**	**$20.36**	**Total fixed costs multiplied by the number of slides in the case**				

APPENDIX 38.1 Microcosting *(continued)*

Variable costs								
Patient slide/pos control	Antibody Diluent, DAKO	$0.15	$0.15	$0.15	$0.15	0.15	$0.15	Approx 299 μL, 110 ml per bottle @ $62.48 per order or $0.15 per slide
	AMCAR antibody	$1.14	$1.14	$1.14	$1.14	1.14	$1.14	266 slides per order @ $303.60 per order or $1.31 per slide
	Envision Dual Link Detection System, Dako code K4061	$3.14	$3.14	$3.14	$3.14	3.14	$3.14	300 μL per slide, 110 ml per order, @ $1,150 per order or $3.14 per slide
	Dako Wash Buffer, code S3006	$0.75	$0.75	$0.75	$0.75	0.75	$0.75	10 liters @ $74.80 per order, runs 100 slides or $0.75 per slide
	Serum Free Block, Dako code X0909	$0.30	$0.30	$0.30	$0.30	0.30	$0.30	300 μL per slide, 110 ml per order, @ $108.24 per order or $0.30 per slide
	DAB chromogen, Dako code K3468	$0.37	$0.37	$0.37	$0.37	0.37	$0.37	300 μL per slide, 110 ml per order, $134 per order, or $0.37 per slide
	NovaRed chromogen, Vector catalog SK-4800	$1.05	$1.05	$1.05	$1.05	1.05	$1.05	100 slides per kit, @ $105 per kit or $1.05 per slide
	Pipette tips	$0.39	$0.39	$0.39	$0.39	0.39	$0.39	7 tips per slide, 1,000 tips per order @ $55 per order, or $0.39 per slide
	Cover glass	$0.26	$0.26	$0.26	$0.26	0.26	$0.26	1 cover glass per slide, 100 glasses per order @ $25.90, or $0.26 per slide
	Total cost per slide	$7.53	$7.53	$7.53	$7.53	7.53	$7.53	
	Total cost for case	**$7.53**	**$7.53**	**$7.53**	**$7.53**	**$7.53**	**$7.53**	**Total variable cost multiplied by number of patient slides**
Negative control(s)	Antibody Diluent, DAKO	$0.15	$0.15	$0.15	$0.15	$0.15	$0.15	300 μL per slide, 125,000 μL per order @ $62.48 per order or $0.15 per slide
	Envision Dual Link Detection System, Dako code K4061	$3.14	$3.14	$3.14	$3.14	$3.14	$3.14	300 μL per slide, 110 ml per order @ $1,150 per order or $3.14 per slide
	Dako Wash Buffer, code S3006	$0.75	$0.75	$0.75	$0.75	$0.75	$0.75	10 L @ $74.80 per order, runs 100 slides or $0.75 per slide
	Serum Free Block, Dako code X0909	$0.30	$0.30	$0.30	$0.30	$0.30	$0.30	300 μL per slide, 110 ml per order, @ $108.24 per order, or $0.30 per slide
	DAB chromogen, Dako code K3468	$0.37	$0.37	$0.37	$0.37	$0.37	$0.37	300 μL per slide, 110 ml per order, @ $134 per order, or $0.37 per slide
	NovaRed chromogen, Vector catalog SK-4800	$1.05	$1.05	$1.05	$1.05	$1.05	$1.05	100 slides per kit, @ $105 per kit or $1.05 per slide

(continued)

APPENDIX 38.1 Microcosting *(continued)*

Test: XYZ Test								IHC				
	ENTER# in one Case	ALL COSTS ARE COST PER SLIDE										
Patient slides	**1**											
Neg control slides	**1.00**											
Separate pos control slides	**0**											
		Number of slides					Enter #					
Item		1	2	3	4	12	15	Comment				
	Pipette tips	$0.39	$0.39	$0.39	$0.39	$0.39	$0.39	7 tips per slide, 1,000 tips per order @ $55 per order, or $0.39 per slide				
	Cover glass	$0.26	$0.26	$0.26	$0.26	$0.26	$0.26	1 cover glass per slide, 100 glasses per order @ $25.90, or $0.26 per slide				
	Total cost per control slide	$6.39	$6.39	$6.39	$6.39	$6.39	$6.39					
	Total cost for case	**$6.39**	**$6.39**	**$6.39**	**$6.39**	**$6.39**	**$6.39**	**Total variable cost multiplied by number of control slides**				
Total variable costs		$13.92	$13.92	$13.92	$13.92	$13.92	$13.92					
Total direct costs		$319.33	$166.62	$115.72	$90.27	$39.37	$34.28					
Overhead	Rate											
Overhead	0.38	$121.34	$63.32	$43.97	$34.30	$14.96	$13.03					
Equipment costs	0.1	$31.93	$16.66	$11.57	$9.03	$3.94	$3.43					
Total		$153.28	$79.98	$55.55	$43.33	$18.90	$16.45					
Cost per case		$472.60	$246.60	$171.27	$133.60	$58.27	$50.73					

APPENDIX 38.2 ROI Calculation Methods

The calculation of the monetary benefit realized as a result of a given capital expenditure is called a return-on-investment (ROI) calculation. When this amount is prespecified, it is known as the required rate of return or discount rate for the investment. Major methods for ROI calculations and typical laboratory examples follow.

PAYBACK METHOD

The number of years that a capital investment takes to be fully recovered from cash flow is called the payback period. The simplest method for calculating the return on an investment is the payback method. When payback periods (number of years necessary for incremental cash inflows to equal the capital acquisition cost) for different candidate items are ranked from shortest to longest, the shortest is the best, and the differences between the shortest payback period and the others represent (at least a portion of) the opportunity cost of each investment.

As an example, consider an immunoanalyzer with a purchase price of $100,000 and an estimated useful life of 5 years. Suppose the estimated yearly incremental cash inflow generated by the machine is as follows:

Year 1 = $55,000
Year 2 = $55,000
Year 3 = $58,000
Year 4 = $60,000
Year 5 = $45,000
Total = $273,000

Estimated yearly cash outflows related to the machine are estimated as follows:

Year 1 = $15,000
Year 2 = $15,000
Year 3 = $20,000
Year 4 = $30,000
Year 5 = $35,000
Total = $115,000

Calculated net cash flow for each year is then as follows:

Year 1 = $40,000 ($55,000 – 15,000)
Year 2 = $40,000 ($55,000 – 15,000)
Year 3 = $38,000 ($58,000 – 20,000)
Year 4 = $30,000 ($60,000 – 30,000)
Year 5 = $10,000 ($45,000 – 35,000)
Total = $158,000

Payback of the original $100,000 occurs between years 2 and 3 is

$$\$100{,}000 = \$40{,}000 + \$40{,}000 + [\$20{,}000].$$

The payback time is

$$\text{Year 1 + year 2 + year 3 } (\$20{,}000/\$38{,}000) = 2.53 \text{ years}$$

This method is most useful when comparing projects with similar useful lives and provides a crude measure of risk in the opportunity-cost estimation. It fails, however, to take into account the effects of depreciation or inflation and, more generally, the time value of money, i.e., the best use of funds, and it does not take into account the impact of any cash flows beyond the payback period.

DEPRECIATION

The rate of depreciation is an additional datum often used in the analysis of capital alternatives. Depreciation recognizes the fact that fixed assets have a finite useful life and accounts for this by charging a fraction of the cost of the capital item as an expense in each accounting period of its use. Useful lives of capital items are difficult to establish precisely, so the rate of depreciation (fraction expensed each year) is usually estimated. Different standard methods for performing this estimation (e.g., for tax purposes) are in use.

Straight-line depreciation is a simple, and therefore very commonly used, method for calculating the expensing of capital items. In the straight-line method, the total cost of the item is simply divided by its estimated useful life in years to give the amount to be expensed as depreciation in each period. For example, in our sample problem, (item's price)/(item's useful life) = $100,000/5 years = $20,000 per year listed as depreciation.

The sum of the years' digits (SYD) method of depreciation is a weighted calculation that assigns a large amount of depreciation in the first year, which then declines uniformly to a small amount for the last year. With this formula, annual rates are derived as follows.

1. Add the ordinal numbers of the years, i.e.,

$$5 + 1 + 2 + 3 + \ldots + [n'(n' - 1)]/2 = S_n$$

2. Write the numbers of the years in reverse order, i.e.,

$$n', n' - 1, n' - 2, \ldots, 3, 2, 1$$

3. The annual fractional rates of depreciation (d) are

$$n'/S_n, (n' - 1)/S_n, (n' - 2)/S_n, \ldots, 3/S_n, 2/S_n, 1/S_n$$

In our example, S_n would be 1 + 2 + 3 + 4 + 5 = 15, and the yearly fractional depreciation rates would be 5/15 (= 1/3), 4/15, 3/15 (= 1/5), 2/15, and 1/15. The actual dollar amounts of annual depreciation would then be as follows:

Year 1: $100,000(1/3) = $33,333
Year 2: $100,000(4/15) = $26,667
Year 3: $100,000(1/5) = $20,000
Year 4: $100,000(2/15) = $13,333
Year 5: $100,000(1/15) = $6,667

AVERAGE RATE OF RETURN

The calculation of the average yearly return on a project divided by the average yearly investment it represents is called the average rate of return (ARR) for that investment. When these ARRs are

(continued)

本书版权归John Wiley & Sons Inc.所有

APPENDIX 38.2 ROI Calculation Methods *(continued)*

ranked from highest to lowest positive values, the highest ARR is the best. In our example, the average annual investment return = (sum of net cash flows)/(useful life) = \$158,000/5 years = \$31,600/year. The average annual investment is calculated as follows:

The initial value of the investment is \$100,000, and its useful life is 5 years, so the annual straight-line depreciation is \$20,000/year. The yearly value of the investment then is as follows:

Year 1 = \$100,000

Year 2 = \$80,000

Year 3 = \$60,000

Year 4 = \$40,000

Year 5 = \$20,000

Year 6 = \$0

The sum of these values for years 1 through 6 total \$300,000, and the average annual investment = \$300,000/6 years = \$50,000/year. The ARR then equals (average annual investment return)/(average annual investment) = \$31,600/\$50,000 = 63%. This method accounts for all the cash flows, but it does not recognize the time value of money.

TIME VALUE OF MONEY (PRESENT VALUE)

The present value of all the cash flows created by a project minus the amount of the initial investment is called the net present value (NPV) of that investment, or the time value of money involved with it. Present value (PV) represents the dollar amount that, if it were invested now at a given rate of return (r), would accumulate to a given specified value a specified number of years (n) in the future. The formula for present value assumes that there are unequal annual rates of cash flow (CF) in years 1 to n:

$$PV = [(CF_1)/(1 + r)^1] + [(CF_2)/(1 + r)^2] + [(CF_3)/(1 + r)^3] + \ldots + [(CF_n)/(1 + r)^n]$$

When NPVs of different projects are ranked from highest to lowest positive values, the highest NPV is the best. In our example, if the required rate of return (r) is 10% and the term (n) is 5 years, the PV would equal the sum of the annual net cash flows according to the above formula:

$$PV = [\$40{,}000/(1.10)] + [\$40{,}000/(1.10)^2] + [\$38{,}000/(1.10)^3] + [\$30{,}000/(1.10)^4] + [\$10{,}000/(1.10)^5] =$$

$$\$44{,}000 + \$48{,}400 + \$50{,}578 + \$43{,}923 + \$16{,}105 = \$203{,}006$$

$$NPV = PV - \text{initial investment} = \$203{,}006 - \$100{,}000 = \$103{,}006$$

This method accounts explicitly for the time value of money and evaluates projects at a common required rate of return, but it does not take into account differences in the size of different investments or allow easy comparison of projects with different useful lives. These considerations must be kept in mind in the final analysis.

Inflation, of course, corrects for changes in the value of money itself over time. The effect of inflation can be calculated as follows. If prices increase at a rate of i per year, and if an item costs P_0 now, then n years from now it will cost $A_n = P_0 e^{in}$, using a general exponential formula for continuous compounding of interest. In our example, if the rate of inflation is 2% per year, the cost of our \$100,000 immunoanalyzer in 5 years will be

$$A_5 = \$100{,}000e^{(0.02)(5)} = \$100{,}000e^{0.10} = \$100{,}000(1.1052) = \$110{,}520$$

本书版权归John Wiley & Sons Inc.所有

APPENDIX 38.3 Financing Alternatives

Methodology based on calculation of the present value is relevant for making choices among alternative sources of funding for capital acquisition.

PURCHASE

In the case of purchase from hospital funds, the present value equals the initial investment. Returning to the example of the immunoanalyzer in Appendix 38.1, purchase with hospital funds involves a cash outflow of $100,000.

For purchase with borrowed funds, the present value equals the annual loan payments plus interest, discounted at the required rate of return for the term of the loan. In the example, for a loan with a term (n) of 5 years, a required rate of return (r) of 10%, and an annual loan payment CF at 12% interest of $27,168, the PV of loan payments, discounted at 10%, is calculated by using the formula for PV with even cash flows:

$$\text{PV} = \text{CF}\ \{[1 - (1 + 1r)^{-n}]/r\} = \$27{,}168\ [(1 - 1.10^{-5})/0.10] = \$27{,}168(3.7908) = \$102{,}988$$

LEASE

A 5-year lease with a required rate of return (r) of 10% and an annual lease payment CF of $24,000 has a PV of lease payments, discounted at 10%, calculated as follows using the formula for PV with even cash flows:

$$\text{PV} = \text{CF}\ \{[1 - (1 + 1r)^{-n}]/r\} = \$24{,}000\ [(1 - 1.10^{-5})/0.10] = \$24{,}000(3.7908) = \$90{,}797$$

Here, the alternative with the *lowest* present value is the best method, in this case, the lease. If this is to be a noncancelable lease and there is no potential opportunity to sell the equipment at the end of the lease term, no further analysis is required. If, on the other hand, the equipment can be sold at the end of the lease (i.e., it has what is known as a salvage market), further analysis is relevant. If the PV for the lease is subtracted from the PV for the purchase, the result will be positive and represent the PV of the amount required to be obtained from the future resale.

This should then be compared with the best estimate of the future market for this resale. If it looks as if the equipment can be sold for more than the required future resale price, then purchase is favored; if not, then leasing is. The lease-or-loan decision can be approached in the same way.

In the example,

$$\text{PV of resale} = \text{PV of purchase} - \text{PV of lease} = \$100{,}000 - 90{,}797 = \$9{,}203$$

The required future value of resale to provide for PV of resale is

$$\text{PV}(1 + r)^n = \$9{,}203(1.10^5) = \$9{,}203(1.61051) = \$14{,}821$$

which is what the future resale will have to fetch at the end of 5 years. For the choice between lease or loan,

$$\text{PV of resale} = \text{PV of loan} - \text{PV of lease} = \$102{,}988 - 90{,}797 = \$12{,}191$$

The required proceeds of the resale will then be

$$\text{PV}(1 + r)^n = \$12{,}191(1.10^5) = \$12{,}191(1.61051) = \$19{,}633$$

Thus, if the resale nets $9,202 or less, leasing is favored; at $9,203, there is no difference between leasing and borrowing; in the range $9,204 to $19,622, borrowing is favored; at $19,633, there is no difference between leasing and purchasing; and at $19,634 or more, purchasing is favored.

本书版权归John Wiley & Sons Inc.所有

39

Outreach: Obstacles to Hospital Outreach and Enhancing Customer Satisfaction

Beth H. Deaton

Introduction
Making Organizational Changes
Centralize Work • Place Laboratory Management on Off Shifts
Give Outreach Its Due
Make Outreach High-Profile • Manage Outreach as a Business, Not a Department
Information Technology Changes
Hospital Systems versus Separate Systems • Non-Staff Physicians • Connectivity • Patient Registration and Accounting • Populating the Patient Record • Physician Office Connectivity
Meeting the Needs
Capital • FTEs
Hospital versus Outreach Contracting
Defining Insurance Plans • Contracting • Acceptance of Payors
Failure to Understand Financial Implications and Requirements
Unrelated Business Income Tax • Other Taxes
Understanding the Hospital's Point of View
Lower Cost per Test • Make Money
Translating Hospital and Laboratory Compliance for an Outreach Operation
Physician Communication • Medicare Secondary Payor Questionnaires • Physician Acknowledgments • Advance Beneficiary Notices • Requisition Design • Pricing • Add-On Tests • National and Local Coverage Policies • Sanctioned Physicians • Contracts • Audits and Reviews • Participation and Cooperation • PAMA—Protecting Access to Medicare Act • Free Lunch and Giveaways
Enhancing Customer Satisfaction: Communication
Newsletter • Marketing and Sales Team • Website
Social Media and System-Developed Communication
Customer Satisfaction Assessment
Surveys • Problem Reporting and Resolution
Couriers: The First Line
Insource versus Outsource for Couriers
Client Services
Access to Draw Sites and Patient Service Centers
Building and Retaining Your Client Base
Leverage the Continuum of Care • Keep Asking Why • Follow Up When Clients Leave
Professional Marketing and Sales Personnel
Commission Plans • Reports • Prepackaged Information
Technical Expertise Accessibility
Accounts That Require Special Care
Nursing Homes • Drug Accounts • Home Health Agencies • Veterinary Laboratory Services
Define Service Area and Services
Range of Services • The Importance of Standardization
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES
APPENDIXES

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch39.

OBJECTIVES

To understand the items that must be in place to compete in the outreach market and why some will conflict with hospital practices and policies

To understand how to capitalize on the strengths of the hospital or health system

To understand the obstacles that must be overcome as part of a hospital or health system

To understand all the pieces for great customer service

To know when to say yes and when to say no to customers

To be able to plan the customer service aspects of the outreach program

Navigating a complex hospital system to set up a service that in many respects is counter to conventional hospital thinking can be a daunting and difficult task. Hospitals have many policies that successfully guide their actions, but hospital laboratory outreach programs compete with large national reference laboratories for their place in the market and need to be able to act and respond comparably. This means changing hospital policies and making exceptions for the outreach business. The level of customer service and the testing the laboratory decides to provide will largely determine the level of success the outreach program will achieve. These are decisions made by the policies put in place and management's actions. The ability of the organization and the staff members to communicate quickly and accurately with their customers and the ability to respond to issues can be deciding factors in the success of the program.

Making Organizational Changes

A hospital outreach program needs to operate differently from a hospital laboratory department. The laboratory needs to evaluate the test menu, where testing is performed, and the turnaround time that is available, as well as its management, equipment, and staffing. In an outreach program, where cost is of primary concern, volume drives cost. Because approximately a third of the cost of producing a laboratory test is fixed, the volume of testing that is produced will be paramount to reducing cost on a per-test level. Fixed costs are costs that do not vary with volume. Examples are depreciation, administration

本书版权归John Wiley & Sons Inc.所有

and management, some full-time equivalents (FTEs) (those necessary for coverage), professional fees (Part A coverage), license fees, controls, and standards. To begin to build volume and expand the test menu, look at other entities within the organization. Other hospitals, physician groups, surgery centers, and nursing homes can provide much-needed volume. However, other facilities will not be eager to give up this volume. They will only be willing to participate if they achieve a financial advantage.

Centralize Work

Review the volume of send-out testing by test. By consolidating to one location, the laboratory may have enough volume to insource additional testing. Then review the more esoteric testing being performed at other facilities in your organization. If there is more than one hospital, clinic, physician office laboratory, or home health agency in the health system, review the testing that is performed in those settings. Centralize as much of the testing as possible to the outreach laboratory. Special chemistry is usually a good place to start. This may need to be done in steps, depending on the politics of the organization and its philosophy about change. Review the testing offered at each site and agree on a standard list of tests that will be performed at each site. In return, the outreach laboratory will have to agree to and meet stringent service standards. By consolidating the test volume, the laboratory will be able to lower test expenses for all facilities by reducing fixed costs on a per-test basis, reducing FTEs, and standardizing.

Place Laboratory Management on Off Shifts

Another area that will need to be reviewed is management. Place appropriate laboratory management personnel on off shifts because that is where the outreach workload will be the heaviest. Management structure needs to be addressed very early in the analysis of outreach. While the laboratory is reviewing the testing from other system facilities, it may be a good time to consider complete laboratory integration. If the laboratory is not ready to go that far, it will need to assess its internal management. More laboratory testing will be performed on the second and third shifts than ever before, so management resources need to be in place on those shifts. Technologists, who are in charge but still working the bench, will not suffice. Someone who has leadership qualities and is authorized to make decisions throughout the entire laboratory should be on each shift, at least Monday through Friday. The reporting relationships can be structured in several ways. For example, each shift manager can be responsible for the human relations duties (hiring, firing, and employment reviews) for the shift he or she is on, as well as be responsible for a specific clinical area (chemistry, hematology, microbiology, etc.). The shift manager can report to a supervisor who has human relations responsibilities while assigning the clinical responsibility to a shift leader or different manager. Another option would be to have all of the staff report to managers who rotate management responsibilities to all shifts.

Give Outreach Its Due

Make Outreach High-Profile

Make sure the outreach laboratory's place in hospital management is high-profile. Outreach programs complicate laboratory operations and increase the level of complexity of every area within the laboratory. For this reason, the laboratory needs to ensure that it has an appropriate place in the organizational structure of the system or the hospital. The person in charge of the laboratory needs to have the ability to access every major department and have resources allocated to the laboratory that are important to ensure that the business can grow and operate efficiently. The person in charge of the laboratory should be at least a director and should attend the workgroup meetings at the appropriate leadership level. If successful (usually based on revenue), there will be a point where the laboratory should be able to break away from hospital management and operate as an entity on its own. Laboratory management must be at an appropriate level in the organization to communicate what outreach testing encompasses and must be able to enlist the help of senior management when needed.

Manage Outreach as a Business, Not a Department

The laboratory outreach program must be viewed and operated as a business, not as a department (cost center) of the hospital. Laboratories in hospitals are typically treated as cost centers. Depending on how an organization displays department financial statements, revenue is sometimes not even on the financial statements available to the department; only expenses are. This gives rise to the attitude, and subsequent management, of the laboratory as a cost center. When the outreach business begins to operate, the financial statements need to reflect the revenue procured by the program, the reimbursement, and the expenses. If this cannot be done on the current hospital monthly financial statements produced by Finance, it is imperative that these data be made available for review to manage the laboratory. Full revenue and expense statements must be available to the laboratory management team to ensure data can be assessed for management decisions and expense monitoring.

Information Technology Changes

Hospital Systems versus Separate Systems

Should hospital systems be used to operate the outreach program, or would it be better to use different systems? A system that allows separation of the billing and financial

本书版权归John Wiley & Sons Inc.所有

operation of the outreach program from the rest of the hospital is optimal. It is best if the laboratory can manage both patient and client billing and receivables separately from hospital-based patients. Hospital systems require a great deal of information that is not always necessary or cost-efficient to collect for reference laboratory patients. Because other reference laboratories do not require the expanded information, if the laboratory is required to collect such information, it will be at a disadvantage in the marketplace.

The average revenue per bill is significantly lower for the laboratory than for other hospital services. Hospital patient accounting departments focus on the high-dollar accounts. Often, reference laboratory accounts are below the level for even a cursory review, leaving the laboratory struggling to obtain reimbursement from payers and patients. If these issues can be addressed with the current hospital system, then you would be wise to use it. Otherwise, investigate the laboratory system or an outsource vendor.

There are several companies that provide an outsource option for laboratory billing. Be sure the company you select has specific experience with laboratory outreach programs and not just physician office laboratory billing. Additionally, be sure to look at the reporting that will be available, how the company will interface with the general accounting system, and how it will receive and provide information for patient accounting. Be sure to delineate all expectations in the contract and consider putting the billing company financially at risk for some indicators.

Client billing is an area where the hospital patient accounting department will have little or no experience. The laboratory's ability to accurately code, bill, adjust, and manage these accounts will be a direct reflection of its ability to compete in the laboratory outreach market. Even if the laboratory is unable to convince Finance to relinquish management of the patient accounts, Finance may be happy to have the laboratory manage the client accounts. This is an area that needs steady management, and the ability to access the laboratory system to review charges and testing performed is advantageous.

Non-Staff Physicians

Non-staff physicians may present a problem when working with the hospital system. The physician database in the hospital information system is built with few non-staff physicians. Most hospitals require all physicians to be approved by the medical staff office to be entered into the system. Outreach will require that the laboratory be able to accept, process, and bill for specimens received from non-staff physicians. The physicians must be put into the database so they can appear on the bill and patient results can be correctly routed. The laboratory must be diligent in updating the database, as physicians will continually enter, leave, and move within the geographic area. You will also need to agree on the information required for physicians to be entered in the database. As recent changes have occurred in the delivery model for physicians that include virtual office visits and more concierge medicine, physicians are moving away from operating an office with a business address or having fax machines. They have moved to complete digital and online models. Systems will need to be able to accommodate these changes.

Connectivity

As the laboratory outreach program grows, the data can be mined from the system for a variety of purposes. Health plans will want the data for utilization and for the employer reporting that it is required to deliver. Physician offices will require interfaces with the system or an intermediate product to interface results. The pharmacy will want to review the microbiology susceptibility profile of organisms to adjust therapies to combat emerging antimicrobial resistance patterns. Nursing homes will also require microbiology data for their population to comply with their regulatory requirements. Others will want the data, blinded and in other formats, to use for research. The system used will determine, to a large extent, the laboratory's ability to provide data to other systems. After HIPAA (Health Insurance Portability and Accountability Act) considerations are reviewed, the next question is what value the laboratory and outreach programs gain from an interface. It will be the responsibility of the laboratory staff to ensure that the data are crossing the interfaces and displaying properly. Each time a change is made to either system, the laboratory will need to keep the interfaces in mind and ensure that data continue to flow properly.

Interfaces with clients are a requirement to ensure the laboratory receives the correct test order, as well as complete billing information, and results are transmitted to become part of the patient's medical record. There are a number of parties that will be needed to coordinate interfaces. In addition to the client and the laboratory, there will be the client's electronic medical record (EMR) vendor, the laboratory information technology (IT) vendor, and possibly middleware vendors. Coordinating all of the parties for information exchange, contracting, and testing makes interfacing complicated and often protracted. Dedicated team members that report to the outreach team should streamline this process and manage implementations.

Patient Registration and Accounting

The demographic data required for most insurance companies for an outpatient bill include patient name, date of birth, address, ordering physician, diagnosis, insurance company, insurance address, group number, and member or subscriber identifier. This list is significantly shorter than the list of requirements for an inpatient admission and some hospital-based service. This seemingly simple

本书版权归John Wiley & Sons Inc.所有

issue can make or break specimen processing. The laboratory must be able to collect only what is required for outreach billing. The list of information for client billing is even more abbreviated, and a separate process will need to be developed to bill these accounts.

Carefully review the Model Laboratory Compliance Program and work with your organization so they are comfortable offering multiple fee schedules. If your organization determines that it is valid to have multiple fee schedules, the laboratory will need to be able to manage the fee schedules. The system chosen for billing must have the capability to have multiple fee schedules, to set up contracts for individual clients, and to apply percentage discounts. It is important to develop and enforce a set of fee policies from the beginning. As part of the compliance program, all fees should be reviewed each year against the policies that have been set and in relation to the cost of testing.

The form used for billing will determine, for some insurance companies, how the laboratory is reimbursed. Hospitals bill using a uniform billing (UB) form because this is the form required for hospitals. Freestanding laboratories and other Part B providers bill on a Centers for Medicare and Medicaid Services (CMS) form. Some insurance plans will require that the laboratory bill on a CMS form and therefore be treated as an outpatient or reference laboratory and not as part of the hospital. These differences are important because they may affect the amount patients are required to pay. Patients' insurance benefits and financial liability are often different if they visit a hospital versus a reference laboratory. Even if the laboratory testing was picked up from the physician office, the insurance company may not make the distinction between the outreach laboratory and the hospital outpatient. The patient will therefore be charged the hospital copay or coinsurance, which is usually higher than if the testing was sent to a reference laboratory.

Populating the Patient Record

The hospital's requirements to populate the patient record with results may prove burdensome. In most hospital systems, client billing is out of the norm. Depending on how your hospital accepts patients billed to a client account (physician office, clinic, or other bulk bill), they may not be accessible as individual patients. Therefore, it is difficult to update the patient record/history that already exists on the system. The laboratory could decide not to populate the patient history with reference laboratory information. This is not the best solution, because one of the advantages for customers is the continuum of care you offer operating within a hospital system. Outreach results in the patient's hospital history offer an advantage that sets an outreach program apart from stand-alone laboratories. There are numerous information technology solutions that can be applied, but they take planning, capital, and forward thinking.

Physician Office Connectivity

Physician office connectivity is a system that allows physicians to register, order tests, and receive results. Physicians' electronic medical records systems or electronic medical records will require inbound and outbound interfaces for their system. The ability to access most solutions via the internet has made placement of computers for physicians less acceptable for compliance. Additionally, testing, installation, and training will need to be supplied either directly by the laboratory staff or through IT.

The information the office inputs will interface with the laboratory system. Depending on the vendor used, clients can register patients, review results online, screen for medical necessity, graph results over time, and have online lookup to the laboratory test guide, as well as many other functions. The patient registration portion may be difficult for the hospital. Allowing nonemployees to create or add to patient records is not acceptable for most hospitals. To compete with the reference laboratories for business, the laboratory will need to support this technology. It will also help the outreach program obtain better registration information, reduce medical-necessity denials, properly identify the testing desired, deliver results, and improve reimbursement. Overall, there should probably be an upside in terms of FTE reductions.

Meeting the Needs

Capital

In most hospital systems capital funding is difficult to obtain, and there is competition for the limited funds. This is why the outreach program must be a priority for the hospital. Defining a process with Finance and Administration to purchase items that are critical to the outreach program will make it easier to obtain items that are vital to outreach programs. Finance and Hospital Administration need to be continuously educated about the outreach business and why items are necessary for program success. One strategy to propose is for the hospital system to allocate a flat amount of capital for the laboratory each year. The laboratory will manage purchases and the capital, making it consistent for the system. However, they will need to be comfortable with the carryover from year to year, and the laboratory will need to be disciplined about budgeting and capital replacement.

Leasing some items is an option, depending on how the organization views these types of agreements. The details of the deal and accounting rules will determine if the lease will need to be fully capitalized. The advantage to leasing is that the leasing company will usually service the equipment for a flat fee. The service is usually worth the price.

本书版权归John Wiley & Sons Inc.所有

FTEs

Anytime the hospital is experiencing a financial slowdown, one of the first things to occur is a freeze on FTEs. Even when no freeze is in effect, approval of FTEs can be an arduous process. This is difficult for a growing business. The laboratory must have contingency plans for replacement of key FTEs, such as couriers, in case open positions occur. Maintaining part-time team members is a great option to flex if you can keep these positions filled. A temporary employment service can help with staffing, but keep in mind the lead time required for training and the additional cost. Temp services can help in other areas. If you plan correctly and have portions of jobs that can be easily delegated and require little training, these responsibilities can be given to a temp. The best, but most expensive, option for courier coverage is to have contracts with one or more local courier services. Form relationships with these vendors and share route information in advance of requiring their help.

Hospital versus Outreach Contracting

Defining Insurance Plans

Research and define the important insurance plans in your area. If the hospital or system owns physician practices, use their information to determine the major insurance companies in the area. If not, the hospital should be able to supply its payor mix. Medicare, Medicaid, and most point-of-service plans accept any provider. If the insurance company allows it, and after checking reimbursement and how the billing system can support it, apply for a provider number separate from the hospital. If the insurance company views the laboratory as a laboratory and not just as part of the hospital, patients may be eligible for lower copayments, but the reimbursement may also be reduced. Review the other insurance companies and identify the most important payors. If you accept lower reimbursement, carefully check to understand how billing will work and ensure the hospital will not be impacted by the lower rates or is prepared to accept the reduction.

Contracting

Obtain permission to contract independently within certain parameters. The hospital contracting department can be a tremendous help, but to the extent possible, have someone who knows the outreach business do the contracting. At a minimum, attend the meetings during contract negotiations. This has several benefits. The laboratory may decide that the administrative burdens of the contract are too costly for the reimbursement offered. Also, if the laboratory has input into the negotiations, you should be able to control the timeline to coincide with the volume you want or need for the laboratory.

Acceptance of Payors

The laboratory does not have to accept all payors but will need to participate with most to secure the business of clients. Plan to be shocked as you review the various terms and pricing structures set out by some of the insurance companies. This is another area that the hospital will have difficulty understanding. The idea that the laboratory can accept reimbursement that is significantly below the hospital fee schedule will be difficult. Know and understand the laboratory costs and the reimbursement that can be accepted. Do not accept low capitation rates or fee schedules that do not cover at least the variable cost with the expectation that the laboratory will make up the difference on the "pull-through" business. First, this can be a compliance problem because government payors may see this as an inducement. Second, there is no way to be assured that the pull-through business will materialize.

Failure to Understand Financial Implications and Requirements

Unrelated Business Income Tax

Unrelated business income tax (UBIT) is an income tax that must be filed annually. Make sure that the corporate finance office understands the outreach business and will file this return for the outreach program if they deem it necessary. Depending on the practices using outreach services, not all of the income will be taxable. The laboratory may be able to exclude some of the clients because they are corporately "related" to the outreach program. Work closely with the finance tax department to clearly understand the income that can be excluded from the calculation. Keep the work papers and reports used to produce this information.

Other Taxes

Other taxes that the laboratory may be subject to include sales tax, business license tax, and personal property tax. Depending on the tax status of the parent company and the laws in your locality or state, some or all of these taxes may apply to the outreach business. The hospital may not have detailed information about some of these taxes, because it may not be required to pay them. But the outreach business may be required to pay some or all of these taxes. Investigate which taxes will need to be paid and, if necessary, build these taxes into the expenses for the outreach program.

Understanding the Hospital's Point of View

There are generally some underlying reasons for, or a charter for, an outreach business. The hospital has expectations that must continue to be met, even as the laboratory progresses from a cost center to a product line.

本书版权归John Wiley & Sons Inc.所有

Lower Cost per Test

Securing the laboratory testing of a hospital or hospital system is usually one of the main objectives of an outreach program. A hospital's cost per test is generally high because of fixed costs and underutilized resources. By adding volume to a facility, you decrease the cost per test, assuming minimal incremental resources are added. Team members and equipment are not fully utilized on off shifts. The balancing act for outreach is to add testing to fill this void. This will work for a while, during the time the outreach program begins to build its business. As outreach grows and outgrows the unused capacity, carefully add testing and resources that make sense. Cost per test should at worst remain static after an initial drop, but even as resources must be added, cost per test should continue to decrease or at least be maintained as a percentage of net revenue. This will be imperative for long-term success.

Make Money

The hospital will, at worst, expect the laboratory outreach business to break even on direct expenses and contribute to hospital and system expenses. In most cases a 3% fully allocated margin is acceptable. It is important to be able to produce financial documents, get them in the hands of the right people, and have more than a break-even financial position. UBIT will be a factor, but there may be other unrelated business lines that are losing money. The hospital may be able to apply the outreach income against those losses to avoid paying UBIT.

Translating Hospital and Laboratory Compliance for an Outreach Operation

All hospital laboratories should have a written compliance plan that follows the Model Laboratory Compliance Program. A current active compliance plan will help keep the laboratory stay on track during outreach implementation; however, the plan will need to be modified, and some policies not previously applicable will need to be added.

Physician Communication

The depth and breadth of physician communication will probably need to be increased as you enter the outreach market. This communication must include information related to compliance policies. Medical necessity and advance beneficiary notices (ABNs) will need to be explained. Billing practices will need to be covered in detail. Specifically, physicians need to know what is included in various panels and when more than one Current Procedural Terminology (CPT) code is billed for a group test. A clinical pathologist contact must be listed, with information on how that person can be reached. Take this opportunity to explain other compliance policies, such as supply orders, standing orders, reflex testing, and requisitions (Appendix 39.1). In addition to circulating the communication to the physician, you should also post it on the outreach website.

Medicare Secondary Payor Questionnaires

Medicare secondary payor (MSP) questionnaires are completed in the current hospital setting when patients first present to the hospital. Hospital outreach programs may not be required to complete the MSP questionnaire if there is no face-to-face contact with the patient. There is still the burden of determining if Medicare is the primary payor, but the questionnaire is not mandatory. Additionally, in cases where a patient visits a draw site or is drawn by a reference laboratory team member in a practice, the form is required.

Physician Acknowledgments

Physician acknowledgments must be completed if the laboratory is going to allow physicians to order non-CPT-approved panels. For instance, if the laboratory allows a physician group to create a panel that includes all the components of the basic metabolic panel plus serum glutamic oxaloacetic transaminase (SGOT), the group must sign a physician acknowledgment. The acknowledgment must include the CPT codes that will be billed, the charges, and the expected Medicare reimbursement. There is also specific language required. It states (i) that the physician understands that the only laboratory tests that should be ordered are those that he or she believes are medically necessary for the care of the patient, (ii) that he or she is aware that using a customized profile may result in the ordering of tests for which Medicare or other federally funded healthcare programs may deny payment, (iii) that as the ordering physician, he or she will order individual tests or a less inclusive profile when not all of the tests included in the customized profile are medically necessary for an individual patient, and (iv) that as the ordering physician, he or she understands that the Office of Inspector General (OIG) takes the position that a physician who orders medically unnecessary tests may be subject to civil penalties. These notices must be completed annually (1).

Advance Beneficiary Notices

Train, train, train, and train some more. Training and using electronic checking from the client interface system are the only ways that the laboratory will receive ABNs as necessary. It is the laboratory's responsibility to properly train the physician offices, when appropriate, to collect and properly complete an ABN. Remember, if the physician does not provide the laboratory with a correct diagnosis code or an ABN, and the laboratory does not get paid, the physician is unaffected. However, there is a provision in the instructions that will allow the laboratory to collect an ABN after the specimen has been received but before

本书版权归John Wiley & Sons Inc.所有

the test is performed. The patient can be called for authorization to perform the test, and then a follow-up ABN can be sent by mail or email (2). This presents obvious processing problems but does leave an avenue to pursue to solve this particular problem.

Beware of locations that collect too many ABNs. An ABN should only be collected *when appropriate* (i.e., when there is a valid reason to believe Medicare will not pay for the test). Also, remember that the instructions require that a copy of the form be given to the patient along with an estimate of the charges. It is the laboratory's reimbursement at stake and therefore the laboratory's responsibility to train the physician office to collect this information when necessary.

Requisition Design

Manual paper requisitions should be discouraged. They are often not completely filled out and legible. If you must use paper requisitions, the requisition design should be carefully planned and evaluated. If a requisition is already in place, a comprehensive review should be completed before using it for outreach purposes. Ensure that billing for panels is properly represented and that all components of a panel, as well as the panel, can be ordered. Make sure the form flows easily for data-processing purposes. Carefully select the tests that will appear on the requisition. Too many or too few tests can be a problem. Leave space for write-ins but place instructions on the requisition that detail the required information for write-in tests. There is required language from the Model Laboratory Compliance Program about ordering tests that must be on the requisition (1). Supply proper space for all of the billing information. Use this opportunity to denote when an ABN might be necessary and when there will be a separate bill from the professional group. Ensure that the laboratory's phone number is on the form. Provision for storage of completed requisitions must also be considered; these requisitions/orders will need to be retained for a minimum of 5 years. Check the latest requirements and the policies of your company to determine your policy. The requisitions must be accessible for audits but not necessarily stored on-site and electronic storage is acceptable.

Pricing

Special pricing should be carefully considered on a case-by-case basis. As part of the compliance program there should be an overriding policy that dictates pricing and discount guidelines (1). Pricing for any client-bill portion of an account must be determined separately from pricing of other testing that will be received. A client bill is for the testing that is billed directly to the physician/client rather than to an insurance company. Do not cost shift between payers (client, Medicare, and other insurance) to win an account. Cost shifting is when the laboratory uses profits from one portion of the account, insurance for instance, to offset shortfalls in profitability from another portion, for instance the client-bill portion. Each part of the testing received must meet compliance guidelines.

Add-On Tests

There must be a policy that covers how add-on tests will be processed. The add-on process is different for the outreach population due to the laboratory's lack of control over the ordering provider and the timeliness of the request. Requests usually lag the time of inpatient orders. A written request is required and the laboratory must be able to produce that order. An internal process to determine specimen availability, viability, and quantity also needs to be considered. This is probably an instance when the technical section should be involved. Even if specimen processing is responsible for locating the specimen, the technical section should set the guidelines that dictate specimen viability and adequacy. Requiring the order to be received before processing the additional test request alleviates the issue of matching the phone order with the written order before billing. Otherwise, a review of the phone orders every 30 days is advised.

National and Local Coverage Policies

Negotiated rulemaking is a process that includes members of the laboratory industry, physicians, and officials from the CMS to develop coverage policies for tests. The coverage policies include the diagnosis codes that will be paid for by the CMS. Local carriers and financial intermediaries are allowed to add to the policies or add new policies but may not delete parts of the existing policy. These policies are updated as often as quarterly. There are services available to ensure that the latest information is available in the system(s) being used for medical-necessity checking.

Sanctioned Physicians

A policy for identification and resolution of specimens received from sanctioned physicians will need to be put in place. Sanctioned physicians are doctors who have been restricted by the OIG from submitting claims and ordering services for Medicare patients. Most laboratory and hospital compliance programs bar the hospital and laboratory from doing business with sanctioned physicians for any testing. Hospital Admissions uses the medical staff office to research doctors and determine their status before granting privileges. In the outreach business, specimens will be presented to the laboratory from physicians who are not on the medical staff. The laboratory will need to be able to identify physicians who have been sanctioned to know whether to process the test. If the test is not going to be processed, you will need to determine how to notify

本书版权归John Wiley & Sons Inc.所有

the physician and handle the disposition of the specimen. STAT and non-re-collectable specimens will require special consideration.

Contracts

A standard client contract will need to be developed and approved by the Legal Department. The contract should be signed by all clients, but it will be a requirement for clients who have a client bill. The agreement should include:

- Length of agreement
- Renewal term
- Termination specifics
- Compliance guidelines
- Services offered
- Fee schedule
- Where to send contract changes
- Governing law
- Limits on the use of the laboratory's name by the client
- Specimen handling requirements
- Billing requirements

If in-office phlebotomy services are included, outline the duties that can be performed, which include only duties directly related to collection and processing of specimens. No office functions can be performed, including rooming patients, answering phones, taking vital signs, etc.

Hospitals will generally have contract tracking systems in which you will need to submit or file the client's contracts. Within the hospital guidelines you will also need to determine who can sign contracts. If you are using a contract approved by the Legal Department, you should be able to have someone from the laboratory sign the agreements. All nonstandard contracts should be reviewed by the Legal Department or its designee to protect the laboratory and the company.

Audits and Reviews

Each of the areas discussed here will need to be reviewed annually, and some areas will require an audit. Add-ons, sanctioned physicians, physician acknowledgments, and requisitions should be reviewed or audited annually. Billing (including ABNs and medical-necessity forms) should be audited at least quarterly. For the items that require an audit, a specified format should be followed and the documentation should be maintained for a minimum of 2 years.

Participation and Cooperation

An outreach program is a large undertaking and will require changes in every area of the laboratory. Some departments that will require detailed review include Specimen Processing, Transfusion Services, Anatomic Pathology, Professional Services, Immunology, and Cytology. Each area will need to review its operations, make decisions, and perhaps create new policies to prepare for the new business.

If successful, the second and third laboratory shifts will change from a slower pace to the busiest time of the day. Successful outreach business is based on the ability of the second- and third-shift team members to complete the bulk of the outreach testing. Equipment, staffing, and facility design will need to be examined to ensure that a larger volume of testing can be produced in the time frame required. A review of on-site testing will also be necessary. With the additional testing that will be procured, tests that were previously sent out will be able to be, and should be, performed in-house. The decreased turnaround time for these tests will benefit not only the outreach program but the hospital patients as well.

PAMA—Protecting Access to Medicare Act

This legislation was enacted in June 2016 and requires "applicable labs" to report their payor data to CMS on a regular schedule. There are four criteria to be an applicable laboratory, including CLIA certification, having a unique National Provider Identifier, as well as revenue and low expenditure guidance. The data are used to adjust (reduce) the Medicare Fee Schedule for labs. Currently most hospital laboratories will not meet the criteria to submit data, but outreach laboratories will most likely meet the revenue threshold for reporting and have their own Medicare number, which will trigger the reporting requirement. The requirements for filling and data required can be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations. If you meet the requirements, reporting is mandatory and carries fines for not reporting. You also need to establish a sign-on for the Medicare website and decide who will authorize the data. They will also need a sign-on. Cooperation from the IT department will be required to correctly retrieve and format the data for submission.

Free Lunch and Giveaways

Providing lunch and giving away pens, sticky notes, and other minor items is permissible if they do not create an inducement (5). Lunch should not be provided without a meeting with decision makers and, at least, some of the providers. A sign-in sheet should be kept every time a meal is provided. Any meals or other items given to physicians will need to be tracked and reported to the hospital/system compliance department. There is an annual limit that can be given to a physician and the system will track to ensure that limit is not exceeded.

本书版权归John Wiley & Sons Inc.所有

Transfusion services. Although Outreach will not get involved in the transfusion of patients, blood typing and screening and ABO and Rh tests will be ordered. Transfusion Services needs to decide how these specimens will be handled in relation to patient history. They will also have specific requirements for specimen labeling and may not accept outreach specimens for transfusion because they do not have control over how patient identification is monitored in the physician office setting. If that is the policy, then outreach specimens for transfusion testing must be ordered and processed differently than for hospital patients. The policies for this area need to be developed and communicated before Transfusion Services receives outreach specimens.

Anatomic pathology. Many of the items discussed for the clinical laboratory also apply to Anatomic Pathology. The same shift of workload, in terms of time of day, will occur in Anatomic Pathology. Additionally, Anatomic Pathology may want to evaluate whether it wants a different numbering sequence for the cases received from outreach. Additional considerations include a separate requisition for pathology specimens, how you will interact and pay for the professional component, registration, and reporting. This is an area where the continuum of care is very valuable for clinicians and should be marketed.

Professional services. Reimbursement for professional pathology services needs to be discussed and decided upon prior to beginning sales for outreach. This is especially true for any client-bill testing. Normally, the professional component for testing is included with the clinical portion for client billing. This means that the laboratory must have a method to capture and pay the professional group for those services. The fee schedule for the professional group must also be completed beforehand so that the fees for the clients can be set to include this cost. If the professional group has a company that does its billing, it may be able to bill the outreach program for the testing. The laboratory may also want to agree with the pathologists about patients' charges and how the demographic and insurance information for patient billing will be transferred to the pathologist.

Multiple pathology groups. If there is more than one pathology group within the hospital system, there will need to be a predetermined method for the distribution of work. Carefully consider how this is done and the rules for competition. Inform the Marketing Department of the method and provide them with guidelines and talking points for the clients.

Immunology. The Immunology Department may or may not be willing to accept specimens from the outreach program. Determine if this is a service that can be offered and what hours it will operate. Usually, Immunology's requirements for specimen transportation are very strict, so transportation may need to be arranged outside of that for the clinical laboratory. Immunology may be interested in using the processes the outreach program sets up for delivery of results and client billing.

Cytology (gynecologic and nongynecologic). Pap smears will be an important part of the outreach business. Determine the acceptable turnaround time for the market. If you are beginning the outreach program as a new program, this is an area where resources may need to be invested. Hospitals do not traditionally perform many Pap smears, so Cytology may lack the ability to easily add volume. The laboratory will need to offer human papillomavirus and liquid-based and image-guided Pap smears. In addition, clients will expect that other testing (*Gonorrhea, Chlamydia, Trichomonas*, etc.) will be performed from the Pap vial. Bacterial vaginosis and vaginitis testing should be done in house due to the cost of send-outs; however, this testing is not covered by all insurance, so you need to determine how patients will be notified. If the hospital offers nongynecologic cytology, this service could be marketed as a niche. Not all laboratories have this capability and the professional expertise that is needed, so this is an excellent service to develop as a niche. This testing is expensive, so do not underprice it, and offer short turnaround time and superior professional expertise for the outreach program.

Enhancing Customer Satisfaction: Communication

It has been said that you need to communicate seven times in seven ways, and it still will not be enough. Keep this in mind when implementing a new program or making changes to existing programs and policies for staff and clients. It will help remind those communicating that once, twice, or even three times is probably not enough. There are some things that can be done to help with this endeavor.

Create a consistent format and brand for all communication. This includes the name of the outreach program, the letterhead, the logo, and the format of the newsletter, guidebook, and any other printed material used for the laboratory program. Use either the hospital logo or one that is created for the laboratory program. If the hospital has good name recognition and a good reputation in the community, the laboratory program should use that advantage. It is important that the same name for the program be used consistently. This consistency will help to begin to create an image and recognition for the outreach program.

本书版权归John Wiley & Sons Inc.所有

Newsletter

In today's environment of email and communication overload, a newsletter needs to be critically considered. If the laboratory is going to publish a newsletter, it should be published on a regular schedule in a consistent format and should deal with issues that are important to the laboratory and the clients. Do not let the client newsletter double as the employee newsletter. It is acceptable to profile the laboratory director, the pathologists, and the other managers, but do not list birthdays, weddings, births, etc. The newsletter should be professional in its writing and presentation. Place the logo and name prominently on the newsletter. Include information about new procedures performed in the laboratory and include technical information in the newsletter. Include policy changes that will affect the clients. Use the newsletter as a marketing tool by explaining proficiency testing excellence, courier on-time information, phone answer times, and turnaround time statistics. However, remember that although the newsletter is delivered faithfully, it will only be read by about 30% of the clients at best. The marketing team can use this as drop-off in addition to digital communication. The cost of mailing the newsletter may not provide a payback.

Marketing and Sales Team

The marketing and sales team should be used to communicate more in-depth issues and to reinforce information that is important to patient care. These team members should be excellent communicators. They need to be comfortable speaking with people of all ages, education levels, and nationalities. There should be a standard communication checklist completed with each client setup. The marketing staff is limited, so they will not be able to visit all of the clients each time a communication is necessary. Also, since this may be the same staff that is responsible for sales, do not consume all of their time communicating to current clients about operations. Use this staff for operational communication only when it is very important.

In the outreach business we tend to use "super techs" for marketing and sales. Outline expectations for marketing team members independently of the current team. Sales and communication are more important than in-depth laboratory experience. The laboratory team has extensive knowledge about laboratory operations, processing, and test requirements. They lack sales experience, an understanding of the sales process relationship building, and knowledge of the medical market. You may need to hire for the latter set of skills and use the current team to train for the former.

Website

The website will take the place of the hard-copy guidebook. Hard-copy guidebooks are no longer necessary, and it is much easier to keep the online information up to date. The website should serve as the client's primary source of information about the laboratory. If successful in its layout and content, the guidebook should reduce calls to the laboratory. Use the logo and name branding discussed earlier on the cover and throughout the guide. The website should contain:

- Comprehensive information about the laboratory and its operations
- Add-on policies
- Supply orders
- Forms
- Testing
  - Specimen requirements
  - CPT codes
  - Testing schedule
  - Turnaround time
  - Reference range
- Specimen preparation, processing, and transport
- Result reporting
- Billing
- Licensure
- Medical necessity
- Inclement weather
- Patient service centers
- Patient confidentiality
- Requisition requirements
- Courier services and stats

Social Media and System-Developed Communication

The Marketing Department for the hospital has established outlets for social media and has access to publications that will reach the physician community, both internal and external. This should include newsletters for the hospital(s), medical staff office publications, and email lists. Work with them for the launch of a new outreach program or significant changes/upgrades to the program.

Customer Satisfaction Assessment

Surveys

Conduct a survey of the clients annually. A customer service survey is a CLIA requirement biannually. Carefully select the questions for the first survey. Changing the survey questions makes year-to-year comparisons difficult and not necessarily valid. The survey should not be longer than 20 questions and should include room for client comments.

本书版权归John Wiley & Sons Inc.所有

Be prepared for a low response rate. A 30% response rate is considered successful. Designing ways to improve the response rate is tricky because most respondents also want to remain anonymous. Evaluate the feedback and make changes in response to the survey data. Completing a survey is only worthwhile if the laboratory uses the results to improve the outreach program. Carefully review the information and work with the lab and administration to make changes that improve services and patient care.

Problem Reporting and Resolution

Have a defined process for problem reporting and resolution. There are a number of policies that should be written and tested before the first phone call is answered. All calls should be logged. If a system is not available for this purpose, create a log that is completed online. Problem reporting and resolution should be a defined cycle. Responses to the typical questions should be quick, efficient, and automatic. Some necessary policies and items to include are listed below. In addition, scripting is a great resource for the Client Services Department and is a method to ensure that consistent service is delivered to each caller each time.

Written policies.

Fax/report delivery problem. The use of faxes and other remote delivery options is an effective and efficient means to communicate results. A policy needs to be in place to monitor and troubleshoot this over the phone. The policy should detail what to do if the initial troubleshooting does not work and should determine if the marketing representative, the phone company, or the equipment vendor should be called.

Calls for result inquiry. This will be the most frequent type of client calls received. Clients inquire about result availability timeline, why they have not received a result, whether a duplicate can be faxed, or what the result means. Because patient confidentiality is an issue, the policy should first detail how to identify the person calling and should ensure that the individual is eligible to receive patient results. This can be determined by having the caller identify his or her client number, doctor number, or even complete street address. The policy should also state what to do if the caller cannot provide this information. After identity is established, the policy should contain information about how to correctly identify the patient in the laboratory system and the acceptable methods for communicating the results. Providing long lists of test results and reference ranges should not be allowed; this is also a problem for microbiology susceptibility results. After the caller is identified, the patient is identified, and the results are appropriately communicated (including a read-back), the laboratory should attempt to determine why the results were not available to the clinician in the office when needed.

Faxing results. A policy for the method and validation of faxing results will be needed. Because so many homes and computers have fax numbers, it is necessary to ensure that all fax numbers are validated before faxing. This process should include sending a test fax and then using that tested fax number to send the patient information. When sending the patient information, it is best if the laboratory does not have to hand dial the number. Work with IT and telecommunications to develop a process to store the fax numbers during the test phase so numbers do not have to be rekeyed.

Wrong test ordered. Write a policy to describe the process to follow if the wrong test is ordered. When the client calls, determine the patient and test in question. Check to see what test was performed or if a test was missed. The original requisition will need to be obtained. If specimen processing ordered the incorrect test, the correct test should be ordered. If the physician ordered the incorrect test, a new order will be needed from the physician. For missed tests, the new test should be ordered immediately and performed STAT if possible. In any of these situations, determine specimen adequacy and viability before indicating that the new test will be performed, and include a step to credit incorrectly ordered tests. Team member education may also be required.

Information. There should be a policy for informational requests. These include questions about turnaround time, specimen collection and preservation, location of the laboratory and collection sites, and services available. When the client service representative provides this information, the call should be logged and information provided to the client regarding where the requested information can be found. The policy should outline when, if the client service representative is unable to answer the call, it is appropriate to send the call to the technical section or other resource and how the call will be handled from that point. The best practice is for the client service representative to use three-way calling or conference call capability to have the client and technical section on the line together so they can hear the answer and take care of any follow-up that may be necessary. This provides the advantage of including technical expertise without just passing the call to the technical section in case further follow-up is needed. If the client needs additional information, the marketing representative should follow up with the client.

Missed pickup. A missed pickup is a difficult service recovery call for the client services staff. This is a good opportunity to develop and practice scripting with the client services representatives so that a consistent and thoughtful message is delivered. The policy for this call will be largely determined by the process in place for

本书版权归John Wiley & Sons Inc.所有

making pickup assignments and the client's status for pickups (daily pickup versus call-in). The specimen(s) should be picked up as quickly as possible, even if specimen viability is not an issue, because the client will view further delay as further lack of customer service. These calls should be logged and tracked for trends that may reveal problems with the predetermined routes or other courier issues.

Lost specimens. This is another good opportunity to develop scripting. If the specimen can be re-collected, the laboratory may offer to call the patient and perform the phlebotomy at the patient's home or office, if necessary, at no charge. The tests should be performed STAT and results communicated by phone and fax. The good news, if there is any, about specimens that cannot be replaced is that they generally stay viable for an extended period. Search all the courier cars, all of the coolers, the client's lockbox (and their next-door neighbors'), the refrigerators in the laboratory and at the client's office, all the technical sections, other laboratories, and anywhere else imaginable. If the specimens cannot be replaced, report to the quality assurance department and complete service recovery as appropriate for the client and the patient. Obviously, this kind of situation needs to be logged and studied carefully, perhaps using a root cause analysis, to determine where the process failed and how this can be prevented in the future.

Other. For problems not covered by a specific policy, there should be a policy that covers how to document an issue and generally what department will handle certain issues. The policy should explain in general the problem-resolution flow and philosophy for handling calls. For atypical or serious problems, there should also be an escalation and problem-resolution cycle that includes notifying management as early in the process as possible.

All calls should be logged, and the data should be reviewed and trended for system or procedural problems that may need to be addressed. Client services should be able to handle more than 95% of the calls that are placed to the laboratory. If not, the team member training and policies should be revisited. Calls should also be monitored routinely using a standard review document. (See Appendix 39.3 for standard document.) Share comments with the team in real time so that team members will be able to recall the client interaction. There should be a clear escalation policy in place for the remaining calls.

Quality assurance. Quality assurance monitors should be developed for the outreach program. Know what is expected of the program and measure against that baseline. Establish thresholds for turnaround time, call abandon rate, on-time courier pickup, call wait time, registration accuracy, missed pickups, and lost specimens. Track numbers on a daily basis. The numbers of tests performed by section per day, the number of requisitions processed, and the number of daily courier pickups will help identify staffing requirements and find weaknesses. Outreach volume is not the same every day, not even Monday through Friday. Know the peak-volume times and days and plan resources accordingly.

Couriers: The First Line

Couriers are the face of the outreach business for the clients. Clients see their couriers daily, and couriers are the only people from the laboratory they see except when they have a serious problem or during marketing visits. Couriers should be neatly groomed, be in uniform, have established communication criteria, and be in vehicles identified with the organization's logo (even if they only pick up from lockboxes).

Give the couriers the respect and resources they need, because the clients will look to them for help when problems occur. When possible for employed couriers, provide them with the ability to access required resources if they have a question or problem. Remember, the entire cycle starts with the courier. The on-time delivery of results for the specimens they are collecting begins with the courier pickup. If the courier is late or a pickup is missed, it sets in motion a chain of events that may culminate with late results or no results due to specimen integrity. Clients expect to have the majority of reports by the next morning when they open. The ability to deliver this level of service depends on all steps in the process being performed quickly and accurately. A delay in any step may not be correctable later in the process.

A specimen tracking system will need to be developed that allows the courier to input the specimens picked up and verify that information with the specimens delivered to the laboratory. Discrepancies must be researched before the end of business for that day.

Insource versus Outsource for Couriers

There are various advantages and disadvantages for both scenarios which will depend on the resources available within the organization, the outsource vendors available, and other factors. To keep courier services in-house, the company will need to invest in vehicles (purchase and upkeep), a route and tracking system, team members, and management. Keeping courier services in-house provides the best line of sight and control over services, but requires expertise that the company does not have, capital, management oversight, and availability to many team members. Outsourcing is the inverse. You have less control, but you will have experts delivering the courier services. Either scenario can work; it depends on your ability to access the resources needed and your comfort level with control.

本书版权归John Wiley & Sons Inc.所有

Client Services

Client Services should be open when the physician office staff begins to arrive in the morning at a minimum. Coverage 24/7 is best but may not be feasible or cost-effective depending on the client base. If the laboratory has nursing home clients, Client Services should be available when the physicians make rounds in those facilities. This is usually before office hours, around 7:00 a.m. The Client Services area can be staffed with some "on-the-job-trained" staff but should also be staffed with medical laboratory technicians (MLTs) or medical technologists (MTs). At least one MT or MLT should be in Client Services during peak call hours. The more technical the staff in Client Services, the more questions they will be able to handle in the department without transferring. The technical staff has the advantage of understanding all aspects of the testing, including specimen collection and acceptability and testing protocols.

Offer clients flexibility in reporting. Mailing of reports should no longer be available due to HIPAA concerns and the delay of patient care. Delivery of reports by courier has some of the same issues and should be avoided. If delivering reports by fax, the fax numbers should be validated when implemented, during each marketing visit, and at least yearly. Delivery using a web portal or the hospital medical record is optimal for timely results in HIPAA-compliant format. Decide how to comply with requests for multiple copies of reports. Will you fax it, print it, or call it in to one, two, or three different locations? What are the processing ramifications of providing this kind of service? Does the laboratory system support this kind of request?

A critical result notification policy will need to be established for the outreach program and may differ from the inpatient policy. The outreach critical result notification policy may include a variance for notification after hours; reducing the number of tests that will need to be called through the night and will need to include an escalation policy when providers cannot be contacted. Involve pathologists or other physicians when the ordering physician cannot be reached to communicate a critical result.

Access to Draw Sites and Patient Service Centers

Draw sites and patient service centers will be vital to laboratory outreach success. Decide on the overall strategy for access to the laboratory by examining options for each of these areas.

Hospital-owned facilities are a great start for patients to access outreach services. Facility locations are generally known, well marked, and easy to find. However, sometimes that is where the advantage ends. A hospital is not always easily accessible in terms of parking and navigating the inside of the building. Do not eliminate the use of the hospital as a draw site, but depending on its layout and accessibility, you may not count on it as a primary source for collections.

Large competitor laboratories often have many patient service centers set up and may allow you to contract with them to perform collections for your patients. This gives you geographically broad, ready-made, pay-as-you-go access for patients. However, remember that this is the competition and clients may ask, "If I am sending my patient to laboratory X to be drawn, why shouldn't I let them do the testing?" Keeping this potential problem in mind, try to open sites specific for your laboratory outreach operation and phase out this type of competitor agreement.

When opening draw sites and patient service centers, remember that location is critical. Select a location that is highly visible, has easy access, and is in an area where the medical community practices. Staff it with friendly, customer service–oriented staff, and ensure adequate staff support as the volume grows. Keep it clean and well organized. Signage should be large, and hours of operation should be listed on the door. Here are a few hints from lessons we have learned.

- Select a location only after reviewing demographic information for patients, physician offices, and specialties. Also keep in mind competing draw sites.
- Complete a proforma.
- Survey the local client offices to discover information about the insurance accepted, if there is a phlebotomist on-site from a competitor, and if they are likely to use your facility.
- Begin communication about the draw site after a firm opening date has been established.
- Execute a formal marketing campaign to announce the new site and entice practices to use the location. The campaign should be 4 to 8 weeks long. Include flyers, client visits, social media, invitations to an open house, and perhaps a free cholesterol screening. The communication about the new draw site needs to be reinforced continuously, but you must provide various communications for the marketing representative to take to the clients. Sending the same flyer or using the same verbal message will not keep the clients interested.
- Use the new site to draw new business. It is the only way the site will pay for itself. Diverting existing business to the site will not result in overall growth or provide any financial advantage.
- Continue to visit practices and encourage them to use the site. Expect that the volume will be very slow at first, but with continued communication, it should grow. Establish targets and timelines for expected

本书版权归John Wiley & Sons Inc.所有

volume and be prepared to reevaluate a site if the targets are not met.

- Since laboratory staff is available to collect demographic and insurance information, it is not necessary that the client complete all of this information on the form. A test requisition gives the client the ability to check the tests needed and the opportunity to include a map to the draw site on the back for the patient.
- Employers may let the laboratory put information about the draw site in their employee newsletter.
- Put an announcement in the section of the newspaper that announces new physicians, if there is one and depending on cost.
- Update insurance provider directories with the new site and put an announcement in the member newsletter.

When a competitor asks to contract for the use of the draw sites, evaluate the value to the draw site and your business versus the advantage to the competitor. It is usually less expensive to pay only for the expenses on a per-draw basis than to invest in a draw site. If you agree, make sure you charge according to the expenses for that site.

Building and Retaining Your Client Base

Leverage the Continuum of Care

If the physician community has loyalty to the hospital or hospital system, start the marketing campaign for the outreach business with the medical staff. Find the practices that primarily admit to the facility. Leverage the continuum of care for their patients. The same laboratory can produce results for their patients regardless of the patients' status: inpatients, same-day surgery, or referred specimens from the physician's laboratory. This way there will never be a problem with reference ranges or varying technology when comparing patients' results from one setting to another.

Keep Asking Why

Continually review and understand why decisions are made. The answers that have been standard over the years may no longer apply for an outreach program. Constantly ask customers about their needs for service, supplies, couriers, client services, and turnaround time. This does not have to be done with a formal survey; client service representatives, couriers, and marketing representatives are great sources of information. Make sure the laboratory is meeting the client's needs and make the client feel involved in the process.

Follow Up When Clients Leave

When customers notify the laboratory that they are leaving or when you determine that an account has been lost, follow up as soon as possible to find out why. Even if the account is not salvageable immediately, taking the time to follow up may help you win accounts back in the future. Follow up again 3 to 6 months after the client leaves and then at least annually. Many "new accounts" will be old accounts that have returned. Also remember to review and discuss the information clients shared about why they left and determine if any other accounts are in jeopardy for the same reason.

Professional Marketing and Sales Personnel

Some laboratories use their current technical staff for sales and marketing. If you are able to find laboratory professionals who possess the skills for selling, they could be transitioned into the sales and marketing role. However, this may not be the best strategy. They will require sales training that may not be readily available. Laboratory professionals are trained to be very detail-oriented and very analytical. They like following procedures and being creative is not encouraged. Not all laboratory professionals fit this cookie-cutter image, but many do, and these are not the same set of skills and traits needed for a sales team member. Hiring sales professionals with proven sales records brings this ready-made expertise to the outreach program. While the laboratory is not an easy area to learn about, laboratory professionals with many years of training should be able to help train the sales staff. Do not underestimate the time required to train a new sales representative. Each person should spend at least a month in the laboratory, followed by quarterly training sessions. The time spent in the laboratory will help sales personnel understand laboratory operations so they can communicate effectively when speaking with clients. It also helps them build personal relationships with the technical staff producing the product they sell.

Training should also take place on how to conduct negotiations and set boundaries for what is acceptable. Some of the training is dictated by the laboratory's compliance program, but there should be additional guidelines set by the sales manager. The sales representative needs to understand that it is acceptable to walk away from a contract, even a large one, if it does not serve the business objectives of the laboratory. These guidelines need to include profitability and service requirements. Negotiations with any client "should not hinge solely on the negotiator's individual skill level" (3). Sales managers should follow up with the client on any negotiations that do not result in a sale.

Commission Plans

Commission plans are no longer permissible due to legislation called EKRA (Eliminating Kickbacks and Recovery Act), which became effective in October of 2018. The lab

本书版权归John Wiley & Sons Inc.所有

industry has concluded that, according to this legislation, commission plans are inducements and therefore no longer permissible. There have been some legal challenges recently, but for now the interpretation stands.

Reports

Sales representatives should be encouraged to stay on the road. Assignment of a personal desk in the laboratory may not be a good idea. Office time should be kept to a minimum. This presents certain challenges for staff management. Over time you will be able to tell if the representative is producing sales. However, you need to keep communication open so you can monitor progress, give feedback, track problems or problem patterns, and ensure that the facilities that management defines as important are visited. Sales (see Appendix 39.2) reports are useful to convey information in a consistent format and to track progress. These reports should be in a standard format and should be completed and turned in at appointed times. The weekly report should include information about each visit made with client decision makers the previous week. Dropping off information to a client office or seeing the receptionist does not count. There should be a minimum number of visits required each week and an accounting of time that is not spent in the field. The monthly report recaps the month's sales efforts. All active prospects should be listed and their status provided. This also serves as the document used to identify accounts that are eligible for commission. Each account should have data available in an online Customer Relationship Management system. The manager should review the information periodically or receive reports to ensure information is being updated. The information will vary but should include basic demographic information, contact information, the names of all the physicians in the group, the hours, and all of the visits made to the account.

Prepackaged Information

Print pieces are a great source of prepackaged information for the sales and marketing team, and a number of pieces should be developed detailing information about the laboratory. Pieces might cover new product offerings, special programs, a niche service, and the professional group, if they provide a competitive advantage. Each piece should stand alone, but identify each with the corporate name and logo, as discussed previously. Vendors may also have pieces that can be co-branded for marketing.

Technical Expertise Accessibility

Identify how and when to access technical staff. The technical staff is a tremendous resource for client services, marketing, and clients. Use them wisely, as this is the same staff the outreach program relies on to produce the high-quality, quick results the clients count on. Identify situations when it makes the most sense to involve the technical staff and contact the right person in the technical section for assistance. For Client Services, contacting the technical section should be done according to a policy. There should be other steps to follow before calling the technical section for help. Marketing team members should build rapport with the technical team during their training and in subsequent training so they will be able to contact them directly for quick answers to questions.

If it is necessary to take someone from the technical staff to meet with a client, the visit should be well planned. The exact source of questions and problems should be researched before a meeting is scheduled. The marketing representative should complete the follow-up whenever possible so the technical staff member can return to the bench. Use this option only for large clients and when the material warrants this level of attention. For instance, a large drug-screen account that has specific requirements might be a good opportunity to bring a technical staff member from Toxicology. They will be able to discuss changes that have occurred with the testing, the technology, and any plans for future changes.

Use the in-area (hometown) availability to your advantage, but do not overburden staff. Being able to provide this level of service to clients is going to be difficult for the competition to match. The large commercial laboratories that have STAT labs in the area do not readily have this expertise to offer. The technical staff is a powerful resource when used correctly. Be careful not to let them become overwhelmed with phone calls and client commitments that could have an adverse effect on test turnaround time. For the most part, the technical staff will welcome the opportunity to answer questions and visit with clients occasionally, which will help to win and keep business.

Accounts That Require Special Care

Each of these account types can be lucrative but also has specific demands that must be met. Before deciding to enter any of these market segments, review the demands and ensure that the laboratory can meet them and still generate a profit.

Nursing Homes

Nursing homes are attractive because of the opportunity to collect many specimens in one location and to control the entire account. The level of service, including phlebotomy, needs to be evaluated in the proforma. To compete in the nursing home business, the laboratory will likely need to commit a phlebotomist to the facility on a regular schedule. For large facilities, STAT phlebotomy will need to be available on weekends and after hours to collect specimens for emergent situations. Results must be turned around the

本书版权归John Wiley & Sons Inc.所有

same day they are collected. The cost of the phlebotomist can be partially offset by a daily fee billed and payable directly by the facility.

The laboratory must contract with the nursing home to provide medical necessity information or pay for the charges that do not meet medical necessity, because collecting an ABN is usually not an option. If the nursing home has Part A/rehab patients, a process must be in place to establish the patient's status at the time the specimen is collected and to check it before a bill is sent. Part A patients are patients for whom Medicare reimburses the nursing home on a case rate that includes all their ancillary services (laboratory, radiology, rehabilitation, etc.). The laboratory will need to bill the facility for the testing performed for these patients. Keep in mind that a patient's status can change retroactively. A commitment must exist from the nursing home to collect MSP information and either make and communicate primary payor information or forward the MSP information to the laboratory. This is a demanding business that has some compliance risks, but we have found that it is profitable for mid-sized to large nursing homes.

Drug Accounts

Drug accounts for preemployment screening also have unique demands. Drug-screen accounts usually require chain-of-custody forms to be completed and can be demanding concerning locations for specimen collection. The more sophisticated employee health programs will want specific testing in place for drugs. Ensure that Marketing and the client understand the difference in testing and pricing between a drug screen and a quantitative drug test.

Home Health Agencies

Home health agencies want easy access to a large number of facilities, quick turnaround time, and delivery of reports to numerous places. Requests to call and send reports to the agency, as well as to several doctors, are not unusual. The advantage to this segment of business is that it is usually delivered to the laboratory. Most home health agencies will deliver the testing to the laboratory. This may be enough of a benefit to offset the requirements of the additional reporting. For clients that want pickups, pricing will need to reflect the on-demand nature of their business.

Veterinary Laboratory Services

Providing laboratory services for the veterinary community is very demanding. The service requirements are extensive and payment is generally low. IT systems will need to be prepared to accept the different breeds and normal ranges required for animals. Also, veterinary pathologists are difficult to recruit and retain, although this segment of the business could be sent to a third party. The business can be a niche service line if you have buy-in from the local veterinary community, you are able to use your current equipment, and you are able to provide STAT service.

Define Service Area and Services

Determine how to define services offered and the service area. Marketing will press for additional services and a larger service area. Any changes to service or service area should be pursued only after a careful marketing and financial analysis. Decisions should be made about the services offered and the territory to be covered based on financial information and resource availability. Stepping outside of the original plan may mean that other services will be compromised or that more resources will be needed. Do not presume that extension of services can be accomplished without sacrifice. If the laboratory has an opportunity and the flexibility to change plans, then the change should be planned and pursued. Flexibility and adaptability are qualities that young businesses tend to be better able to attain than established businesses. Take advantage of that strength but understand the consequences before a change is made.

Range of Services

What other services will you offer? System courier, home draws, arterial blood gases, and pulse oximetry are some of the services your program may have the ability to provide. As we evaluated these services, we determined that most of these were not our core business, as they were expensive or administratively burdensome. Some laboratories have been willing to invest the resources to make this a niche for themselves in their system.

Courier for the system. The courier service for the laboratory can be expanded to serve the health system, and there are advantages and disadvantages that should be considered. If the laboratory decides to take on the responsibility of transporting items other than laboratory supplies and specimens, ensure that there is a tracking system in place. Some items cannot be replaced. Transporting other items while transporting specimens can provide a good business case for a specimen-tracking system, which will be an added benefit to your clients. If the laboratory can adequately provide this service or join a systemwide courier network without sacrificing the timeliness of pickup and delivery of specimens, it could be a win for everyone. Remember, though, that if couriers do not have the ability to do their laboratory job well, the laboratory will be behind schedule from the time the specimen arrives, and making up that time is not easy.

Pulse oximetry. The laboratory sometimes will take on the responsibility of pulse oximetry, since the same people

本书版权归John Wiley & Sons Inc.所有

performing this function also collect arterial blood gases. Pulse oximetry testing is needed to certify patients for oxygen. However, there is limited reimbursement from Medicare in terms of both the value of the reimbursement and medical-necessity requirements. Additionally, the task is administratively burdensome. The patients often need the equipment delivered and picked up from their homes. Then there is the issue of ensuring that the results are reported as needed. This service can be an added benefit for existing clients, but the number of people who will use the service does not usually provide sufficient benefits to distinguish the program in the market.

Arterial blood gases. Some hospital laboratories include this function because it is related to phlebotomy, but usually it is provided by the Respiratory Department. Someone will need to be available in the hospital at all times for this service. The skills that are required are different from those of phlebotomy. More in-depth training is required to collect arterial blood gases, so the function is generally limited to a subset of the phlebotomy staff. Nursing homes will want this service and will view it as an added benefit of dealing with the outreach program. Most reference laboratories do not provide this service. This draw is usually not scheduled, unlike the daily draws performed for nursing homes, and as discussed, the entire phlebotomy staff will probably not be trained to do this testing, thus making the service difficult to deliver. The respiratory vendor that the nursing home contracts with will also offer this service, and it may be advisable to direct inquiries for this service to them.

Home draws. Doctors and home health agencies will be very pleased with the laboratory for providing this service. If the laboratory can rigidly control the service area and hours of operation, meet medical-necessity standards, and only provide the service for offices that have signed contracts for their complete business, it may be worthwhile. Profitability is difficult with this business because of the time and distance involved in collecting the specimens and the limited number of tests that will be drawn at each stop. This could be offered as a premium service with a self-pay fee for each patient. Enlist the aid of the Compliance Department to determine the rules for homebound patients, certification for homebound status, and the billing of travel fees. There is also a safety factor to consider for the phlebotomist. Consider the neighborhoods they will be asked to visit and the fact that they are in the homes of strangers. Do not ask that they collect funds, even if the patient is self-pay.

In-office phlebotomy. This is a service that will help win accounts and may be required for larger practices. Be careful not to run afoul of the compliance issues and ensure that the physician office is large enough to support the cost of a phlebotomist. This service should normally be offered to accounts with three or more providers in the office each day, keeping in mind the practice specialty. Family practice, internal medicine, oncology/hematology, infectious disease, rheumatology, and large OB/GYN groups are all excellent opportunities for placement of a phlebotomist. Surgical groups are usually not a good option because although they generate a large volume of testing, the blood-bank criteria may be difficult to meet even if the patient is being admitted to your facility. Even very large pediatrics, psychiatry, dermatology, and orthopedic medicine groups generally do not generate enough volume to make placement of a phlebotomist profitable. Gastroenterology, urology/nephrology, and other specialties may work out, depending on the size of the practice and the types of services they offer. Understand your break-even point for an on-site phlebotomist. When profitability is calculated, remember to consider not only the time for the phlebotomist who is assigned to the office but also the cost of coverage when that person is sick or on vacation. Also consider what happens to that team member if the office is closed on a day the team member would normally work.

The Importance of Standardization

Some companies build their reputation on their ability to personalize service and are sometimes able to charge a premium rate for the additional service. To some extent, the laboratory needs to be prepared to personalize service and should determine in advance what personalization could be offered. But because reimbursement is largely fixed based on a fee schedule or a capitated rate for an insurance company, recouping additional expenses will be difficult.

Product offering. Decisions need to be made about the testing that will be performed and the schedule that will be offered. What testing will be offered STAT? STAT fees can be charged but will not be reimbursed by insurance companies so they will need to be billed directly to the client. In Virginia, the STAT fee cannot even appear on the bill for Medicaid patients. Decide on fees for services and discount schedules. Decide what the discounts will be based on, keeping in mind the compliance restrictions.

Process. Testing referred to the laboratory should be handled in a consistent format for ease and accuracy of processing. However, the laboratory will have many requests to alter the process to accommodate clients. Use of electronic orders is ideal, but a standard requisition will also need to be developed. There may be compliance concerns if clients do not use the standard requisition, because the laboratory will be required to determine from the

本书版权归John Wiley & Sons Inc.所有

client's form the testing that needs to be completed and the required compliance language will not be on the form. Clients may send separate printouts with demographic and billing information. This usually allows for better, more legible information, but the client's printout may not have all the information required. Identify how to meet clients' needs if they want to change the order format or add specific identifying information on the report. A physician office connectivity system will help meet some of these needs. For clients receiving reports by fax, there should be multiple print times available. Have a process to allow delivery of reports to more than one doctor.

A process will need to be developed to collect information not received on the original request. This policy must address two kinds of issues. First, a policy will be required for situations when information needed to run the test (test name, patient name, and patient identifier) is not received or additional patient history is required. Second, a policy will need to be developed for when proper billing information, including ABNs, is not received. If the test information is not received, the laboratory will have to determine if any testing will be done. For instance, if a lavender tube is received, should a complete blood count be performed? If this is done, billing must be held until an order is received. If an ABN is needed but not received, and the test is performed, the laboratory will risk not being paid. Some laboratories will send a comment about the problem on the report and call the physician office for the missing information.

For every step of the process, the laboratory will receive requests to alter the process. To the extent that the laboratory can customize its service without compromising overall service or quality, the program will be better able to compete. Ensure that the laboratory can consistently deliver the service promised and administer the agreed-upon exceptions.

Courier routes. Practices across the service area will close at approximately the same time and want their specimens picked up as they leave the office. Knowing that is not possible, the laboratory needs to design the routes so that the majority of the specimens are picked up as quickly as possible and returned to the laboratory for processing to begin. Couriers will need to be equipped to handle a number of requests and issues. If a client is not ready when the courier arrives, the courier must decide whether to wait for the specimens, try to come back, or call another courier to pick up the specimens. If a client who routinely leaves specimens in a lockbox daily does not leave the lockbox out, an attempt should be made to contact the practice by phone. If that is unsuccessful, the courier should have preprinted notes, or a notice printed on demand, to leave on the door or in the box. The laboratory will also need to decide how to handle calls for STAT transports or requests for multiple pickups in the same day. Depending on the size of the account, multiple pickups may be a good idea for both the client and the laboratory, so processing of the specimens can begin sooner. Requests for STAT pickups should be monitored and addressed if problematic.

Monthly tracking from your vendor or tracking system should be reviewed each month for adjustments in service. Some of the information that is useful might include:

- Number of stops
- Stops by time during the month
- STAT calls
- STAT calls by mileage
- STAT calls or on-demand calls by client
- Routine courier pickups that are not being used or have low utilization

SUMMARY

Successful establishment of an outreach program can have numerous benefits for the hospital laboratory, the hospital system, the physicians, and the community. Leverage the intellectual and capital assets of the hospital while working internally to offset any challenges that being part of a hospital system present. The decisions made regarding how to maintain and service customers while still being able to expand the business are important and will affect the program's overall success. Choose the service offerings and service standards carefully and always deliver what is promised.

KEY POINTS

- Deciding how to implement an outreach program within the current hospital environment requires decisions at many levels of the organization. Contracting, information technology, finance, and compliance are key areas that require attention. Understanding each of these areas is critical to success.
- Being part of a hospital system offers advantages to the physician base and to the patients. Leverage those advantages to make a winning and profitable business.
- Consider all of the points and options for customer service. Customer service is not only a department or something people do in their spare time. It must be a united, consistent strategy employed to win and keep customers.

GLOSSARY

Add-on test A physician adds on after the initial laboratory order is received.

Advance beneficiary notice (ABN) Notice that must be provided to patients for testing that is not medically necessary so that the laboratory may bill the patient should Medicare deny payment.

本书版权归John Wiley & Sons Inc.所有

Client bill Bill sent to the client for payment of laboratory services as opposed to billing the patient or the patient's insurance.

Commission plan A written plan for calculation and distribution of commission payment to marketing staff and other individuals.

Continuum of care A patient's continuum of care includes the hospital, physician office, skilled-nursing facility, outpatient surgery, primary care, specialty care, and any other health service a patient may need.

Fixed costs Costs that remain constant in spite of changes in output (4).

Full-time equivalent (FTE) A standard 2,080-hour work year. This may be one team member that works a standard 40 hours per week each year or a combination of team members that equal 2,080 hours per year.

Guidebook A book that provides comprehensive information about the laboratory and its operations, policies (including forms), testing, specimen preparation, result reporting, billing, staff, and licensure.

Health Insurance Portability and Accountability Act of 1996 (HIPAA) A law to improve the flow of information between insurance companies and providers and protect the privacy of patient information (5).

Medical necessity Services that are "covered, reasonable and necessary for the beneficiary, given his or her clinical condition" (1).

Medicare secondary payor (MSP) Information that is collected from the patient to determine when Medicare is not the primary payor.

Model Laboratory Compliance Program A statement of expectations published by the CMS (Centers for Medicare and Medicaid Services) for laboratories to use as a model for behavior.

Non-staff physicians Physicians who are not part of the hospital medical staff.

PAMA—Protecting Access to Medicare Act Legislation that requires reporting of payor data to CMS.

Physician office connectivity System that allows clients access to the laboratory information, usually via the Web. The system should also provide the client the ability to register patients, order tests, and print results.

Pull-through The testing that is sent to a laboratory because the client already has to use the laboratory for other testing. Usually associated with a laboratory that has a health maintenance organization (HMO) contract. Clients that have a large volume of testing for that HMO may send the laboratory testing for other patients whose insurance does not require a specific laboratory.

Sanctioned physicians Physicians who have been barred from billing Medicare, Medicaid, or other government payers, usually for compliance/billing issues. Other providers and people can also be barred from the government programs.

Unrelated business income tax (UBIT) An income tax that must be filed and paid annually for net income that is not related to the hospital. Laboratory testing and revenue generated from physician offices, clinics, and employers that do not have a corporate relationship with the laboratory or parent company would be considered unrelated.

REFERENCES

1. **Taulbee, P.** 1998. *The HHS Office of Inspector General's Compliance Program Guidance for Clinical Laboratories*. https://oig.hhs.gov/documents/compliance-guidance/965/cpcl.html. Accessed 1 November 2023.

2. **Department of Health and Human Services**. 2021. Guidance Portal: Revised form CMS-R-131 advance beneficiary notice of noncoverage. https://www.hhs.gov/guidance/document/revised-form-cms-r-131-advance-beneficiary-notice-noncoverage. Accessed 1 November 2023.

3. **Ertel D.** 1999. Turning negotiation into a corporate capability. Reprint number 99304. *Harvard Bus. Rev* May–June.

4. **Kieso DE, Weygandt JJ**. 1983. *Intermediate Accounting*, p 347, 4th ed. John Wiley & Sons, Inc., New York, NY.

5. **Office of Inspector General.** 2023. Fraud & abuse laws. https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/. Accessed 1 November 2023.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 39.1 Sample Physician Letter

Note: This client letter is for demonstration purposes only. Actual names, phone numbers, and CPT codes may have changed.

Dear Physicians:
XYZ Laboratories is proud to serve the Northern Virginia community as the only full-service reference laboratory. Each year we disclose information about our billing practices and compliance policies as required.

This letter provides healthcare professionals with written information addressing various policies that affect ordering, performing, and billing clinical laboratory tests. Details regarding XYZ Laboratories policies are attached.

Dr. [ABC] is our Medical Director and Clinical Consultant. She can be reached at 703.000.0000 for questions about testing.

If you would like more information about the topics covered in this compliance communication, I may be contacted at 703.000.0000 or by email. If you have questions about any services we offer, please contact our Client Service department at 703.000.0000 and they can connect you with a Marketing Representative. Additionally, more information is available on our website.

Sincerely,

APPENDIX 39.2 Sales Report

Sales Rep Weekly Report—Due Friday by 5 p.m.

Name: Date:

5 New Prospects

Client Name EMR	Volume	Date Visited	Notes

Top 10 Qualified Prospects—This may include clients from above. Qualified prospects must have (i) Meeting with Decision Maker (ii) Indicated level of interest in IL (iii) Next step planned within 1 month.

Client Name EMR	Volume	Influencer/ Decision-Maker	Next Steps

(continued)

本书版权归John Wiley & Sons Inc.所有

APPENDIX 39.2 Sales Report *(continued)*

Plans for the Week—Target Geography or clients

Client Name or Area	Notes

Contracts out for Signature

Client Name EMR	Date Contract to Client	Rep Assigned	Projected Start Date	Next Steps

Implementation in the next two weeks

Client Name EMR	Start Date	Result Model	Rep Assigned	Date of Contract	Implementation Plans

Post Implementation clients

Client Name EMR	Start Date	Volume Proforma	3 Month Volume	Next Steps

本书版权归John Wiley & Sons Inc.所有

APPENDIX 39.3 Monthly Call Review

Client Services Monthly Call Monitor							
Rep							
Date	Time	Length	Greeting	Tone	Resolved	Signoff	Notes
Rep							
Date	Time	Length	Greeting	Tone	Resolved	Signoff	Notes
Rep							
Date	Time	Length	Greeting	Tone	Resolved	Signoff	Notes
Rep							
Date	Time	Length	Greeting	Tone	Resolved	Signoff	Notes
Rep							
Date	Time	Length	Greeting	Tone	Resolved	Signoff	Notes
Rep							
Date	Time	Length	Greeting	Tone	Resolved	Signoff	Notes

本书版权归John Wiley & Sons Inc.所有

本书版权归John Wiley & Sons Inc.所有

IX

Clinical Trials and Evidence-Based Laboratory Medicine

(SECTION EDITOR: **Donna M. Wolk**)

40 The Current State of the U.S. Food and Drug Administration Process and Regulations for Diagnostic Laboratory Assays
Donna M. Wolk, Natalie N. Whitfield, and Fran White

41 The Clinical Trial Laboratory: Research Compliance for Clinical Microbiologists
Donna M. Wolk, Amanda M. Styer, and Natalie N. Whitfield

42 Clinical Trials and Evidence-Based Research in the Clinical Laboratory
Donna M. Wolk and Natalie N. Whitfield

本书版权归John Wiley & Sons Inc.所有

本书版权归John Wiley & Sons Inc.所有

40

Introduction
Background: The FDA Processes for Classification and Assessment of New IVDs
Premarket Approval • Premarket Notification 510(k) and 510(k) Review • Alternate Application Submission Approaches • The "Presubmission (Q-Sub)" Process • The Expedited Review
The Emergency Use Authorization Act
Miscellaneous FDA Requirements
Establishment Registration • Medical Device Listing • Good Manufacturing Practices (GMPs) and Quality • System Regulations (QSRs) • Quality Control
Automated Laboratory Assays
Postmarket Review
Limitations Inherent to Current FDA Processes
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES

The Current State of the U.S. Food and Drug Administration Process and Regulations for Diagnostic Laboratory Assays

Donna M. Wolk, Natalie N. Whitfield, and Fran White

OBJECTIVES

To understand the role of the U.S. Food and Drug Administration (FDA) in the regulation of in vitro *diagnostic devices (IVDs)*

To understand the process by which the FDA approves a laboratory assay

To describe the different approaches used during the FDA review

To describe the risk categories upon which the FDA determines the type of process for review

To understand the premarket approval (PMA) forms, requirements, and process

To recognize the importance of Good Laboratory Practices (GLPs), Good Clinical Practices (GCPs), Good Manufacturing Practices (GMPs), and quality systems regulations (QSRs) in the FDA approval process

To understand requirements related to 510 notification to the FDA

To understand the preinvestigational device exemption process

To review various and multiple FDA requirements

To understand the role of the Center for Devices and Radiological Health (CDRH)

Above all, don't fear difficult moments. The best comes from them.
Rita Levi-Montalcini

Much attention and effort are focused on the interface between scientific methods and their transition to clinical diagnostics supporting diagnosis, prognosis, population screening, therapeutic decision making, and therapeutic monitoring practices. The U.S. Food and Drug Administration (FDA) regulates the release of *in vitro* diagnostic devices (IVDs), commonly referred to as *laboratory assays* or *tests*. Tests cannot be sold or distributed until receiving FDA clearance or approval. For new diagnostic laboratory tests to achieve the optimal utility for the purposes listed above, clinical laboratory scientists (CLS), laboratory managers, and administrators must fully understand the process and regulatory framework defined for diagnostic

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch40.

本书版权归John Wiley & Sons Inc.所有

assays. This chapter provides an overview of (i) the FDA process for risk-based classification and regulation of IVDs, (ii) the FDA methods used to assess the performance of IVDs before their clearance or approval for release to the market for diagnostic use, (iii) the laws that impact assay manufacturers and clinical laboratories participating in clinical studies to generate data to support an FDA submission, and (iv) the process by which FDA conducts postmarket regulation of IVDs and associated postmarket performance.

For an updated review of FDA-approved and cleared molecular assays for infectious diseases testing, a recent review details the state of the art in FDA-approved laboratory methods (1). To maintain accuracy to the laws and regulations surrounding the submission review and clearance/approval of new laboratory diagnostics, this section was, in part, excerpted and paraphrased from the FDA (2).

Background: The FDA Processes for Classification and Assessment of New IVDs

Under the Federal Food, Drug, and Cosmetic Act, the FDA maintains regulatory authority for IVDs and IVD components distributed via interstate commerce (2). IVDs are medical devices defined in section 210(h) of the Federal Food, Drug, and Cosmetic Act (2). Like other medical devices, IVDs are subject to premarket and postmarket controls, and laboratories performing diagnostic testing are subject to the regulations outlined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under the oversight and authority of the Centers for Medicare and Medicaid Services (CMS) (3). In addition, IVDs may also be biological products subject to section 351 of the Public Health Service Act (4).

The Center for Devices and Radiological Health (CDRH) performs review of new IVDs via premarket review within one of three divisions: Microbiology, Chemistry, and Immunology (Hematology and Pathology). For IVDs that relate to the human blood supply and retroviral testing, the premarket review is performed by the Center for Biological Evaluation and Research (CBER) (5).

The FDA classifies IVD products as Class I, II, or III, according to the risk level; regulatory control is necessary to assure safety and effectiveness for their intended use and application (i.e., what is being tested) and their indicated use (i.e., why a patient is tested). Class I represents those IVDs with low risk, Class II with moderate risk, and Class III with the highest potential risk. Greater scrutiny is usually given to high-risk IVDs with the most FDA oversight logically focused on Class III IVDs.

Class I devices present minimal potential harm to patients or persons being tested. Class I products are often substantially equivalent to previously FDA 510(k) cleared products. Most Class I IVD products are exempt from required premarket review but are subject to FDA general controls, which means their use must comply with FDA quality system regulations (QSRs). Manufacturers of Class I products must register the manufacturing company with the FDA and list the product with the FDA before releasing the product for sale or distribution.

Select Class I products may not be exempt from the FDA premarket review process. Class I products that are not exempt are subject to premarket review before product release. Examples of Class I exempt IVD products include unassayed, qualitative, third-party controls (as long as they are not used for blood screening), general-purpose laboratory reagents, and other low-risk products. Analyte-specific reagents (ASRs) may be exempt if the intended use is broad and not specific to an assay. Like other Class I products, third-party control materials and ASRs are exempt from FDA review; however, they must be manufactured per FDA QSRs.

Like Class I devices, Class II medical devices are also products that are substantially equivalent to previously approved products; however, from the FDA's perspective, they require additional review, study, and control, which may include the need for a clinical trial. Most Class II products are subject to FDA scientific review via the 510(k) review process. Most IVDs are Class II products that require 510(k) review, but a few IVDs require a premarket approval (PMA). All IVDs must be manufactured in a QSR-compliant environment. An example of a Class II IVD product is an infectious disease genotyping assay.

The FDA has created a special category for products with moderate risk and considered a Class II product, but for which a predicate device (an FDA-cleared substantially equivalent product) is not available. Such new technology, for which a predicate device is not available, may be reviewed under the De Novo 510(k) review process. The De Novo 510(k) pathway is similar to the traditional 510(k) review process but requires the company to provide a risk/benefit analysis to support the performance data. As an example, the De Novo pathway was used to obtain the first FDA clearances of microarrays and microarray instrumentation.

Class III medical devices are products for which no substantially equivalent product is available and usually involve new technology specific to a high-risk diagnosis. A PMA requires a rigorous review process and usually requires more data, manufacturing information, risk analysis, and other components to achieve approval. For example, currently a molecular assay for detection of *Mycobacterium tuberculosis* requires an FDA PMA submission. It is important to note that even after an initial product receives FDA PMA, subsequent products still require a PMA. Only when a Class III product is down-classed, there is a transition to the 510(k) review process.

The classification and intended use of an IVD determine the appropriate FDA premarket review pathway and

本书版权归John Wiley & Sons Inc.所有

the data and depth of detail required for a successful FDA review and clearance. The Code of Federal Regulations lists the classification of existing IVDs in three sections, 21 CFR 862 (6), 21 CFR 864 (7), and 21 CFR 866 (8), as well as other supporting documentation (9); therefore, manufacturers can generally assess a product classification with accuracy. If a product classification is unclear, a manufacturer can request the FDA review for classification through the FDA 513(g) process. FDA will review the product description and intended use and provide the manufacturer with a determination of product classification.

To date, randomized controlled trials (RCTs), such as those used for pharmaceuticals, have not been required to generate data to support diagnostic assay performance. Instead, method comparison study designs (diagnostic accuracy experiments) are usually performed. Typical method comparison studies may not be appropriate for all new assays. In most cases with infectious disease products, the FDA requires the performance of a new assay be compared to a defined reference (gold) standard rather than just comparing the performance of a new test device to a predicate device (10, 11). For example, for a rapid antimicrobial susceptibility (AST) assay, the FDA requires performance to be compared to reference method, which is broth microdilution, instead of an FDA-cleared AST system. Although the FDA process and diagnostic clinical trial designs may change in the future, the current FDA process is described in the following sections.

Premarket Approval

A PMA is an application submitted to the FDA requesting approval to market or continue marketing a Class III medical device (those with substantial importance to prevention or impairment of health or that has the potential for unreasonable risk of illness or injury and for which general and special controls are considered inadequate). A PMA may be required for a device that tests for a new analyte or substance or that claims a new intended use of an existing analyte for which a previous FDA review process has not been approved.

A PMA requires the most supporting information and receives the highest level of regulatory review. For most PMAs, sponsors identify surrogate endpoints and establish the device performance (e.g., clinical sensitivity and specificity, or positive or negative agreement) related to the specified endpoints in corollary studies using randomly collected clinical samples. Studies are required to demonstrate safety and effectiveness. If the FDA finds that a product is safe and effective, the company then receives approval to market the device in the United States.

Proof of substantial equivalence is required for most IVD products. The types of studies necessary to demonstrate substantial equivalence commonly include analytical studies performed by the manufacturer using clinical samples and, in some cases, spiked samples prepared in a test matrix. Additionally, in almost all cases, for most IVD products, a method comparison or clinical study is required to generate data to demonstrate product performance compared to a gold standard method or a predicate device. In many cases, the FDA will require that prospective samples be tested. These may be leftover laboratory samples that meet defined inclusion criteria or may have to be collected specifically for testing a new IVD. Study protocols should be designed to generate data that will support the clinical validity of a new device.

A PMA review is based on composite scientific evidence, providing a reasonable assurance that the device is safe and effective for its intended use(s). PMA applications must include information and data describing the preclinical evaluation of the IVD (i.e., testing performed by the manufacturer before the clinical trial), as well as evaluation of clinical performance in representative United States laboratories testing patient samples per the device's intended use. A study protocol must detail testing procedures specific to the test device and a defined reference method. The protocol must outline sample inclusion and exclusion criteria. In some instances, stored biorepository samples or a body of literature may be included in the final product assessment.

For IVD products, the device's safety relates to the impact of the device's performance, i.e., that the assay can accurately and reproducibly measure the target analyte under defined and controlled conditions stated in the package insert for the product. The impact of false-negative and false-positive results on patient health is critically reviewed.

FDA lead reviewers aim to review PMA submissions in a 180-day timeline. If there are unaddressed issues, the FDA lead review scientists can ask for additional information and place the submission temporarily on hold. It should be noted that this happens in most PMAs submitted to the FDA for review. If a device is first-of-a-kind or presents unusual safety and effectiveness issues, it may require an advisory panel review. The advisory panel includes external experts in the field that review submissions and recommend final disposition to the FDA. Review panels often include medical laboratory scientists, biostatisticians, medical officers, and biomedical engineers. The FDA is not required to follow the recommendations of the advisory panel, but it generally does (https://www.fdli.org/2019/05/pma-advisory-panels-do-their-votes-matter/).

The device should have clear and documented clinical validity and utility (effectiveness) to be approved for use. Clinical trials are often performed under regulations provided by Good Clinical Practices (GCPs). Approval of a PMA also requires a review of the Good Manufacturing Practices (GMPs), an inspection of the manufacturing facility, a bioresearch monitoring audit of clinical data

本书版权归John Wiley & Sons Inc.所有

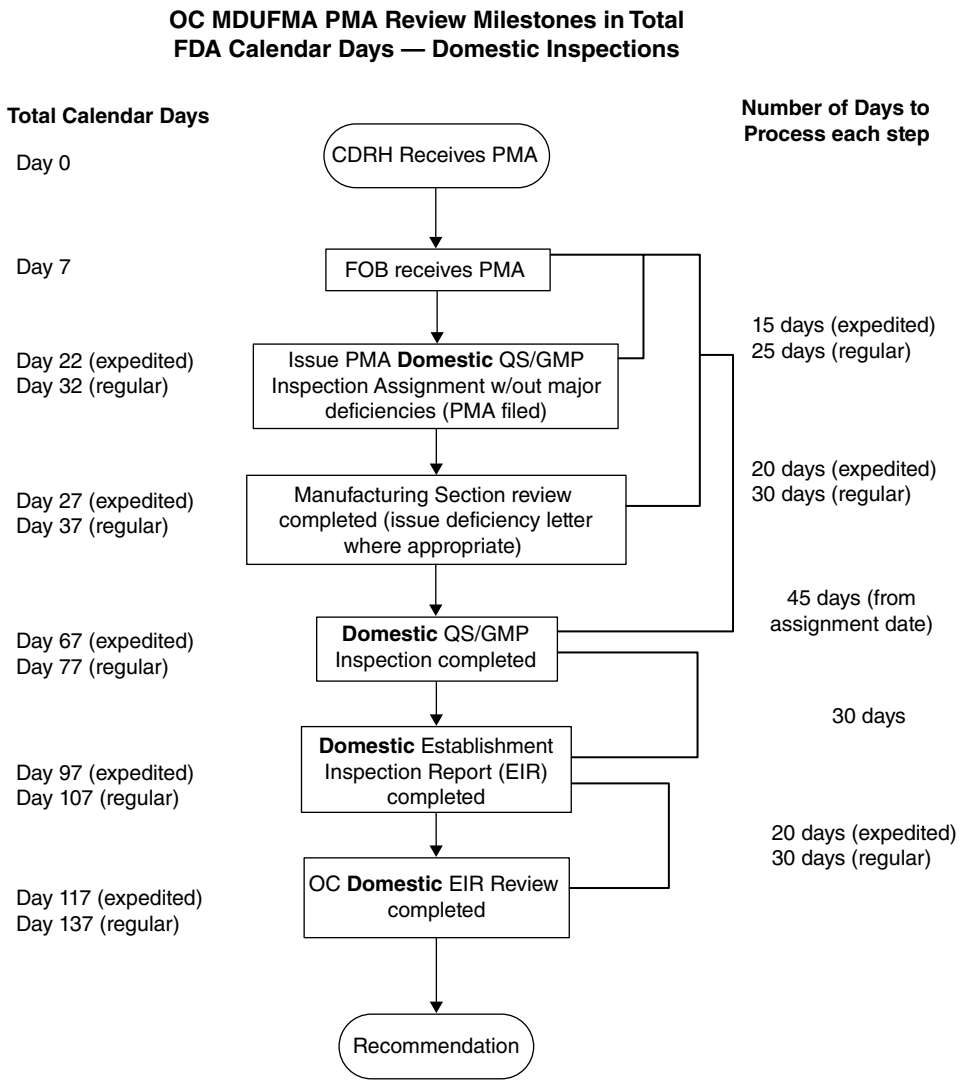


Figure 40.1 PMA review milestones in total FDA calendar days—domestic inspections. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077795.pdf (accessed 18 December 2022).

sites, and a comprehensive review of the premarket data. Compliance with QSRs can be accessed via an inspection process. A manufacturer considering a PMA should consult 21 CFR 814 (12). A flow diagram outlining the PMA process is shown in Fig. 40.1.

Premarket Notification 510(k) and 510(k) Review

A 510(k) premarket submission must provide data and rationale to demonstrate substantial equivalence to a legally marketed device (FDA cleared) with a similar intended use. Data included in the submission must support the safety and effectiveness of the assay. A company with an FDA Class I or Class II product will likely need to submit a 510(k) to the FDA for review. Many Class I and select Class II IVDs are exempt from 510(k) review. Based on the product's intended use, the manufacturer must determine the FDA product code and define the regulatory path before legally marketing the assay. Once an assay is FDA-cleared, if a manufacturer changes the intended use or significantly modifies the device, a new 510(k) may be required. No formalized 510(k) form exists, but the submission format is described in 21 CFR 807 (13). Select low-risk Class I and Class II products are exempt from 510(k) premarket review. However, before marketing an exempt device, the manufacturer must comply with FDA QSRs, register the manufacturing facility with the FDA, and list the device. Most ASRs do not require premarket review but must comply with ASR-specific requirements.

In most cases, a 510(k) must include clinical and analytical data. The test device performance must be compared to a defined laboratory standard or a predicate device to demonstrate clinical performance. It is important to note that while it is required to demonstrate equivalence to a

本书版权归John Wiley & Sons Inc.所有

predicate device, in many cases FDA will require performance to a defined laboratory standard. For many IVDs, the FDA defines performance standards that must be met to obtain clearance. In most cases, the FDA will require that clinical performance be compared to a reference standard or predicate device and must ensure >90% accuracy, sensitivity, and specificity.

Analytical data must be generated to support:

- Limit of detection
- Analytical sensitivity and specificity
- Reproducibility
- Product and sample stability
- Carryover studies and cross-contamination
- Other studies may be required based on the product's intended use.

The FDA review of a 510(k) is initially expected within 90 days, but sometimes the agency may have questions and require additional information to finalize the submission review. A request for additional information from the FDA can extend the review time beyond 180 days. If the product does not meet performance requirements or is not demonstrated to be substantially equivalent to a legally marketed device, the company will receive a letter from the FDA indicating that the device is not substantially equivalent to another legally marketed device. In that case, the device cannot be marketed in the United States until such time FDA premarket clearance is received.

Alternate Application Submission Approaches

While the FDA understands that new devices with the potential for significant and positive public health impact should be made available to the market as quickly as possible, the review process must be completed. The COVID-19 pandemic has delayed FDA submission review for many IVDs, but there is hope that the approval process will return to a near-normal pace by 2024. Manufacturers understand the approach to FDA clearance or approval and plan to ensure products that meet the required specifications with analytical and clinical data generated according to FDA guidance. To obtain FDA clearance for a new device that can be demonstrated to be substantially equivalent to an FDA-cleared device, a company can consider two regulatory pathways: an abbreviated 510(k) (14, 15) or a traditional 510(k). Importantly, most new microbiology/virology and immunology devices require a traditional 510(k) submission.

As an initial step in determining the most appropriate regulatory pathway, companies must consult 21 CFR 807.81(a) (13) and classify the test device. If a device is not classified as a Class I or Class II device, it may automatically be classified as a Class III device and could require a PMA. However, the FDA De Novo program does allow for lower-risk devices for which a predicate cannot be identified and their product classification is not possible, to possibly be reviewed through the De Novo process.

The "Presubmission (Q-Sub)" Process

The "preinvestigational device exemption" (pre-IDE) process is one of two processes to facilitate market entry for products with a positive public health impact. Presubmission documents and meetings are voluntary, and most IVDs are exempt from pre-IDE regulations. The pre-IDE is an informal presubmission process for IVDs, during which time FDA can assign the processes with an official tracking number, similar to numbers assigned to 510(k)s and PMAs. A sponsor company (manufacturer) submits a pre-IDE when FDA's feedback on study design or regulatory strategy can be solicited.

Sponsors should submit a presubmission document only if they would like the FDA's views about their studies or proposals before starting their studies. The presubmission process can involve meeting with FDA to discuss protocols and possible regulatory pathways or sending analytical or clinical protocols to FDA for review and comment before proceeding with studies. Manufacturers who engage in this process with the FDA are not required to submit a pre-IDE application subsequently. Any comments or recommendations made in the review of protocols or during these meetings are not binding on either side, the manufacturer or the agency. A submission made under the presubmission process is not an official pre-IDE as described in 21 CFR Part 812 (16,17). It is important to note that the presubmission process is entirely confidential and no information specific to the product or presubmission is released. Protocol review or a presubmission meeting is requested under the following circumstances:

1. The new product involves new technology, and it will be helpful to familiarize FDA with the technology in advance of the submission.
2. Assistance is needed in defining possible regulatory pathways.
3. The study designs are complex, and advice is required to identify ways to simplify them and keep costs reasonable.
4. The studies involve complex data and/or complex statistical approaches.
5. To reduce the cost of research studies by focusing on the important information needed for FDA approval (or clearance).
6. The meeting can help to expedite the review.

本书版权归John Wiley & Sons Inc.所有

The Expedited Review

The FDA review of a PMA or 510(k) application may be expedited for a new device upon sponsor request or based on the FDA preliminary review. If granted, an expedited review means that the submission moves to the head of the review queue, and additional resources may be applied to accelerate the review process. To merit expedited consideration, the condition to be diagnosed by the product must be irreversibly debilitating or life-threatening. The device must address an unmet medical need, as demonstrated by any one of the following: (i) breakthrough device designation, (ii) no approved alternative, (iii) significant clinically meaningful advantage, or (iv) in the best interest of patients. Since COVID-19-related expedited reviews have been limited, review time for all submissions has been extended.

Although expedited review assures that the device of interest receives a high priority, it does not guarantee a particular review outcome or timeline. The most critical determinant of review time is the quality of the data provided as well as the quality of the submission. It is strongly recommended that companies use all requisite scientific, statistical, and regulatory resources appropriate to ensure that submissions are clear, complete, and can be reviewed quickly. Sponsors with devices eligible for expedited review are encouraged to work with the FDA through the Breakthrough Device Program (18).

The Emergency Use Authorization Act

The FDA's Emergency Use Authorization (EUA) authority enables the FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear threats, including infectious diseases (19). The EUA facilitated the use and availability of medical countermeasures needed during public health emergencies. EUA information falls under section 564 of the Federal Food, Drug, and Cosmetic Act. If and when the Secretary of Health and Human Services (HHS) declares that an EUA is appropriate, the FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used during the emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents. Criteria to deploy the EUA include conditions when there are no adequate, approved, and available alternatives. The HHS declaration to support such use must be based on one of four types of determinations of threats or potential threats by the Secretaries of HHS, Homeland Security, or Defense. FDA issues guidance to diagnostic laboratories that use test methods under the EUA (20).

Miscellaneous FDA Requirements

Establishment Registration

Establishments involved in producing and distributing medical devices intended for commercial distribution in the United States are required to register with the FDA. Registration provides FDA with the location of medical device manufacturing facilities and importers. Registration of an establishment is not an approval of the establishment or devices listed nor does it provide FDA clearance to market. Unless exempt, premarketing clearance is required before a device can be placed into commercial distribution in the United States (21).

Medical Device Listing

Most medical device establishments required to register with FDA must list the devices they have in commercial distribution, including devices produced exclusively for export. Device listing provides the agency with device sales and distribution information. FDA- cleared/approved devices must be listed.

Good Manufacturing Practices (GMPs) and Quality System Regulations (QSRs)

The GMP requirements are part of the QSRs. They require that domestic or foreign manufacturers have a quality system for designing, manufacturing, packaging, labeling, storing, installing, and servicing finished medical devices intended for commercial distribution in the United States The QSR is contained in 21 CFR 820 (22) and related documents (23).

Quality Control

Quality control (QC) is a material or mechanism that, when used with or as part of a test system, monitors the analytical performance of the system. QC material should monitor the entire test system. QC testing must be part of a clinical and analytical test plan. While companies must provide QC samples or recommendations, FDA does not have jurisdiction over laboratory QC testing. That function resides under CLIA oversight. Other agencies with deemed status, such as CMS, the College of American Pathologists (CAP), The Joint Commission, and COLA, formerly the Commission on Office Laboratory Accreditation, have jurisdiction over the procedures and practices within laboratories. While in many cases, laboratories must follow the manufacturer's instructions for use, most often, manufacturers recommend that QC be performed according to the laboratory, state, and local requirements.

Automated Laboratory Assays

The FDA regulates automated instruments and related onboard software when the CDRH classifies devices for use in clinical laboratories. A risk-based regulatory approach to these products is used to ease the burden on the industry while ensuring public safety. Stand-alone

本书版权归John Wiley & Sons Inc.所有

automated clinical analyzers are categorized as exempt Class I devices and do not require a premarket review [510(k)]. When an automated clinical analyzer measures a specific analyte, the analyzer plus the associated reagents become a test system that requires a 510(k) submission, including clinical and analytical data supporting assay performance when run on the automated analyzer with final validated software specific to the assay included in the submission. Automated clinical analyzers are not exempt from premarket notification when they include any Class I-reserved or Class II device. Automated clinical analyzer software for Class III devices may require premarket approval.

Postmarket Review

The revised regulations for GMPs are an important regulatory tool. The QSR, 21 CFR 820, was developed and established to ensure the quality production of medical devices. Developed in alignment with international standards for quality systems, the QSR emphasizes the need to build quality into product design by introducing various processes and production/manufacturing controls. It also includes corrective action requirements for deviations. For selected Class I, and all Class II and Class III devices, the QSR calls for the implementation of design controls that dictate that the manufacturer of a product will identify both device inputs and outputs, ensure verification of performance, and establish validation of performance to predict and ensure proper use in the hands of the end user.

Postmarket monitoring of FDA-cleared devices requires that companies monitor product performance and report product failures. Companies must investigate failures and take appropriate corrective actions to address product failures. The FDA reporting system, MedWatch (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program), documents issues and can be used by phone, fax, or internet. For IVDs, monitoring of MedWatch reports is now performed by more than a half dozen technical analysts participating in premarket review and compliance actions. Hopefully, these and other efforts will lead to improved postmarket regulatory oversight, more sophisticated outreach and educational initiatives, and ultimately more informed premarket decision making.

Limitations Inherent to Current FDA Processes

There are several unavoidable limitations to FDA's 510(k) application review. Since the FDA does not have the facilities to perform wet laboratory product evaluation, it bases its review on the materials submitted by the industry sponsor. There are few performance standards to ensure that regulatory decisions are based on clearly defined scientific parameters (24, 25). Potential limitations to FDA's review of PMA applications include (i) lack of a "gold standard" against which to judge performance; (ii) bias, which may occur in the collection of data to establish safety and effectiveness; (iii) problems in the study design or conduct; and (iv) the challenge of determining the minimum performance required for approval.

SUMMARY

While often statistically and operationally more straightforward than the pharmaceutical clinical trial and FDA submission process (26), the FDA processes to classify, assess, clear, or approve IVDs present a challenge to manufacturers and end-users. With the increase in new products and new technologies, combined with the increased requirements for clinical and analytical data to support performance and demonstrate the safety and effectiveness of a new device, there is increased demands on the clinical laboratory community to help manufacturers and participate in performing required clinical studies (5, 27). Limitations of the process and the clinical trials represent aspects of clinical laboratory practice that may impact clinical laboratory staff once the product is released. Therefore, it is prudent for all laboratorians to understand the FDA process that the manufacturers follow to bring a new diagnostic test to the market. Laboratorians should be willing to consider how they can participate and add value to the clinical study and FDA process.

New products are essential to the healthcare industry, improving laboratory diagnosis and patient care. Participating in clinical trials gives you access to new products before market introduction. Importantly, conducting clinical trials can be a source of revenue for the laboratory. Effectively performing clinical studies requires strict compliance with the study protocol, often does not duplicate final product workflow, and requires extensive documentation. The manufacturer's clinical protocol should be designed to capture the data the FDA will require for the final product approval (clearance). This overview is not intended to supplant the regulations that apply to these processes, but rather to provide an overview and general understanding. Consultation with a regulatory specialist or the FDA will always be required to confirm processes and details of the regulations.

The FDA aspires to provide the least burdensome premarket reviews and brings considerable resources to help bioindustry and manufacturers of IVDs establish performance. The FDA develops standardized review processes based on state-of-the-art evaluation techniques, grounded in the Food and Drug Administration Modernization Act of 1997 mandate. There are over 70 recognized standards and multiple review guidelines that provide assistance. A search engine available at http://www.accessdata.fda.gov/

本书版权归John Wiley & Sons Inc.所有

scripts/cdrh/devicesatfda/index.cfm (accessed 23 December 2022) links to summaries of cleared or approved products and provides the medical community with insight into the classification, review, and approval process for a wide variety of laboratory products.

The FDA process is intended to prevent bad outcomes if diagnostic assays are not adequately vetted and assessed for accuracy and utility. Although error in laboratory testing is not completely avoidable, and the process for FDA approval is lengthy, we are reminded of the benefits in a quote from Rita Levi-Montalcini who stated, "Above all, don't fear difficult moments. The best comes from them."

KEY POINTS

- The process used by the FDA to bring a new diagnostic assay to market is explicit.
- Guidelines are accessible, and assistance is available throughout the entire process.
- Using GLP and GMP guidelines ensures accuracy and quality assurance.
- Utilizing the preapproval submission process provides clinical information on the requirements to generate data to support assay performance, safety, and effectiveness.

GLOSSARY

See also the FDA Glossary of Terms for further information and related definitions: https://www.fda.gov/patients/clinical-trials-what-patients-need-know/glossary-terms.

510(k) A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective as—that is, is substantially equivalent to— a legally marketed device.

ASRs (analyte-specific reagents) ASRs are the "active ingredients" of tests that are used to identify one specific disease or condition. ASRs are purchased by manufacturers who use them as components of tests that are cleared or approved by FDA and by clinical laboratories that use the ASRs to develop LDTs used exclusively by that laboratory.

CBER Center for Biological Evaluation and Research.

CDRH Center for Devices and Radiological Health.

CMS Centers for Medicare and Medicaid Services.

Emergency Use Authorization (EUA) The FDA's EUA authority enables the FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear threats, including infectious diseases. The EUA facilitates the use and availability of medical countermeasures needed during public health emergencies.

IVD (*in vitro* diagnostic) Medical devices as defined in the Federal Food, Drug, and Cosmetic Act; they are subject to premarket and postmarket controls. *In vitro* diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, to cure, mitigate, treat, or prevent disease or its sequelae.

Laboratory-developed test (LDT) An LDT is a type of *in vitro* diagnostic test that is designed, manufactured, and used within a single laboratory.

Premarket approval (PMA) A PMA is an application submitted to the FDA requesting approval to market or continue marketing a Class III medical device (those with substantial importance to prevention or impairment of health or that has the potential for unreasonable risk of illness or injury and for which general and special controls are considered inadequate). A PMA may be required for a device that tests for a new analyte or substance or that claims a new intended use.

REFERENCES

1. **Emmadi R, Boonyaratanakornkit JB, Selvarangan R, Shyamala V, Zimmer BL, Williams L, Bryant B, Schutzbank T, Schoonmaker MM, Amos Wilson JA, Hall L, Pancholi P, Bernard K**. 2011. Molecular methods and platforms for infectious diseases testing a review of FDA-approved and cleared assays. *J Mol Diagn* **13**:583–604.

2. **FDA**. 3/29/2018. Federal Food, Drug, and Cosmetic Act (FD&C Act) *on* Food and Drug Administration. https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act. Accessed 18 December 2022.

3. **CDC**. 11/14/2022. CLIA Law & Regulations. https://www.cdc.gov/clia/law-regulations.html#. Accessed 18 December 2022.

4. **Snyder LP**. 1994. Passage and significance of the 1944 Public Health Service Act. *Public Health Rep* **109**(6):721–724, 109.

5. **Mansfield E, O'Leary TJ, Gutman SI**. 2005. Food and Drug Administration regulation of in vitro diagnostic devices. *J Mol Diagn* **7**:2–7.

6. **FDA**. 2023. CFR—Code of Federal Regulations Title 21. Part 862, Clinical Chemistry and Clinical Toxicology Devices. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=862. Accessed 18 December 2022.

7. **FDA**. 2023. CFR—Code of Federal Regulations Title 21. Part 864: Hematology and Pathology Devices. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=864. Accessed 18 December 2022.

8. **FDA**. 2023. CFR—Code of Federal Regulations Title 21. Part 866: Immunology and Microbiology Devices. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=866. Accessed 18 December 2022.

9. **FDA**. 2018. General Controls for Medical Devices. https://www.fda.gov/medical-devices/regulatory-controls/general-controls-medical-devices. Accessed 18 December 2022.

10. **Meier KL, Gitterman S**. 2011. Drug-device trials for infectious diseases: CDRH perspective. *Clin Infect Dis* **52**(Suppl 4):S367–S372.

本书版权归John Wiley & Sons Inc.所有

11. O'Kane D. 2010. An outsider's viewpoint: the FDA should regulate clinical pharmacogenetic/genomic tests, but… *Clin Pharmacol Ther* **88**:746–748.

12. FDA. 2023. CFR—Code of Federal Regulations Title 21. Part 814: Premarket Approval of Medical Devices. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=814. Accessed 18 December 2022.

13. FDA. 2023. CFR—Code of Federal Regulations Title 21. Part 807: Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807. Accessed 18 December 2022.

14. FDA. 2020. How To Prepare a Special 510(k). http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134573.htm. Accessed 18 December 2022.

15. FDA. 2019. How to Prepare an Abbreviated 510(k). http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134574.htm. Accessed 18 December 2022.

16. FDA. 2020. IDE Approval Process. Pre-submission process. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm#pre_ide. Accessed 18 December 2022.

17. FDA. 1995. Goals and Initiatives for the IDE Program #D95-1 (blue book memo). https://wayback.archive-it.org/7993/20191212033112/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/goals-and-initiatives-ide-program-d95-1-blue-book-memo. Accessed 18 December 2022.

18. FDA. 2023. Breakthrough Devices Program. https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program. Accessed 03 May 2023.

19. Foucar E, Wick MR. 2005. An observational examination of the literature in diagnostic anatomic pathology. *Semin Diagn Pathol* **22**:126–138.

20. FDA. 2023. Emergency Use Authorization. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization. Accessed 03 May 2023.

21. FDA. 2022. Device Registration and Listing. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm. Accessed 18 December 2022.

22. FDA. 2022. Code of Federal Regulations, Title 21—Quality System Regulation. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820. Accessed 18 December 2022.

23. FDA. 2022. Quality System (QS) Regulation/Medical Device Good Manufacturing Practices. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm. Accessed 18 December 2022.

24. FDA. 2022. Premarket Notification (510k). http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm. Accessed 18 December 2022.

25. FDA. 2022. How to Prepare a Traditional 510(k). https://www.fda.gov/medical-devices/premarket-notification-510k/how-prepare-traditional-510k. Accessed 18 December 2022.

26. Campbell G. 2008. Statistics in the world of medical devices: the contrast with pharmaceuticals. *J Biopharm Stat* **18**:4–19.

27. Bastian H, Glasziou P, Chalmers I. 2010. Seventy-five trials and eleven systematic reviews a day: how will we ever keep up? *PLoS Med* **7**:e1000326.

本书版权归John Wiley & Sons Inc.所有

41

Introduction
Organizational Resources for Funded Clinical Research in Laboratory Medicine
Office of Sponsored Projects • Office of Research and Contract Analysis
Compliance with Human Subject Regulations
Background for Human Subject Regulations • Regulatory Requirements for HSPPs • Human Subject Research: Classifications Based on Risk • Human Subject Training Requirements and Site Authorization • Informed Consent • Special Populations • Continuing Review by the IRB • Record Retention for HSPPs
Compliance with HIPAA
Compliance with Conflict-of-Interest Policies
Intellectual Property Considerations
GLP and GCP Regulations
Sponsor Responsibilities • Study Director Responsibilities • Quality Assurance Office: Organization, SOPs, Inspections, and Reporting Data • GLP Background • Equipment and Validation of Equipment • Standard Operating Procedures • Reagents and Solutions for Tests and Controls • Final Research Reports
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES
APPENDIX

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch41.

The Clinical Trial Laboratory: Research Compliance for Clinical Microbiologists

Donna M. Wolk, Amanda M. Styer, and Natalie N. Whitfield

OBJECTIVES

To describe the research compliance responsibilities for human subject protection laws

To help the reader understand the key restrictions of the Health Insurance Portability and Accountability Act (HIPAA)

To help the reader understand the definition of a conflict of interest

To list the key aspects of good clinical practice (GCP)

Have confidence in your ability to do your job right, and work hard to do the best possible job.

WALT DISNEY

MANY ASPECTS OF RESEARCH COMPLIANCE IMPACT clinical researchers whose practice is based in academia, private reference laboratories, or hospital-based diagnostic laboratories (1–7). Since many clinical researchers may also have operational responsibilities in clinical laboratories and may be responsible for aspects of clinical practice, it is often essential for the guidelines and regulations for clinical research to align with the objectives of clinical practice. However, boundaries between the two functions remain imperative. Clinical laboratory directors, consultants, and managers who perform research are responsible for compliance. They are often defined as a project's principal investigator (PI), co-principal investigator, coinvestigator, consultant, collaborator, or research staff. No matter what the role, research compliance is an important responsibility.

Critical components of clinical research include compliance with human subject protection laws, the Health Insurance Portability and Accountability Act (HIPAA), conflict-of-interest policies, good laboratory practices (GLPs), and research integrity (i.e., responsible conduct of research). Compliance with regulations regarding biosafety, biosecurity, import and export controls, chemical safety, and other areas is relevant but is not reviewed here.

This chapter is intended as an overview of general aspects of clinical research processes, but it is not to be considered all-inclusive; those performing clinical research must follow the rules and regulations defined by their organization, their professional societies, and the federal government.

本书版权归John Wiley & Sons Inc.所有

Rules can change rapidly; therefore, each investigator must keep current and informed of relevant compliance issues.

Organizational Resources for Funded Clinical Research in Laboratory Medicine

Office of Sponsored Projects

A sponsored project is any externally funded research or scholarly activity with a defined scope of work or set of objectives that provide a basis for sponsor expectations (1, 8). More specifically, this activity involves research, demonstration, professional development, instruction, training, curriculum development, community and public service, or other scholarly activity involving funds, materials, other forms of compensation, or exchanges of in-kind efforts under awards or agreements. The office of sponsored projects (OSP) supports faculty and staff throughout the award life cycle, from application to closeout.

The OSP has various functions, which may vary from organization to organization. Most commonly, the OSP serves to review, negotiate, and approve terms and conditions for grants and cooperative agreements. The OSP accepts awards as an authorized official on behalf of the organization and serves as the primary contact for sponsors in consultation with the PI and department business office staff. It also assists with the interpretation of sponsor requirements and federal regulations and ensures that the organization and the funding sponsor policies, procedures, and processes are followed.

There are many types of funded research: federal and nonfederal funding (grants and contracts) and industry-sponsored clinical trials or research contracts. The presence of any one of the following conditions typically identifies the activity as a sponsored project.

- The proposal is submitted in response to a proposal request or similar solicitation.
- The proposal commits the organization to a specific line of scholarly or scientific inquiry, typically documented in a statement of work to be performed.
- The proposal includes objectives that provide a basis for sponsor expectations.
- The proposal commits organization resources, such as personnel effort or use of equipment, facilities, or other resources.
- The proposal includes a detailed budget.
- The proposed project involves using human subjects, laboratory animals, radioactive or hazardous materials, recombinant DNA, carcinogens, pathogens, or proprietary materials.
- A specified performance period is typically defined by start and end dates.
- The sponsor requires deliverables stated in an agreement, such as reports, financial accounting, or intellectual property ownership.
- The award restricts or monitors publications or the use of results or requires the protection of confidential information.
- The award provides for the disposition of tangible or intangible property that may result from the project, such as equipment, records, formal activity reports, theses and dissertations, rights in data, software, copyrights, inventions, or research-related materials.
- The award specifies fiduciary responsibilities, such as adherence to a line-item budget, project audit, payment contingencies, and the return of any unexpended funds at the end of the project.
- The sponsor makes decisions regarding project performance or stands to derive benefit from the work performed.

Sponsored awards are made to the organization on behalf of the PI, who is primarily responsible for carrying out the award's requirements. The PI may also be referred to as the project director. In developing a proposal and administering an award, the PI represents the organization and is responsible for upholding the high standards expected of projects. The PI also serves as the fiscal officer of the project, with all the attendant responsibilities of the project's fiscal management. The few exceptions are specific awards that may be made to individuals, such as some faculty fellowships.

Sponsored projects are subject to "facilities and administrative" (F&A) costs at the organization's rate applicable to the type of project being conducted. Suppose the sponsor has a published federally negotiated policy, uniformly applied, prohibiting or restricting the payment of F&A costs. In this case, the organization will accept the reduced F&A rate per the sponsor's policy. This policy does not apply to for-profit sponsors, who are expected to provide full F&A recovery.

Office of Research and Contract Analysis

The office of research and contract analysis (ORCA) is an administrative resource to ensure that organizations conduct their educational, research, and business processes in a manner that is consistent with regulatory, statutory, and organization requirements. This collaborative effort is designed to achieve compliance and establish standards guiding research activities to protect the rights of the researchers, the environment, and the community.

An organization's ORCA typically provides support for the following areas: human subject protection program (HSPP) compliance, the institutional review board (IRB), the institutional animal care and use committee (IACUC),

本书版权归John Wiley & Sons Inc.所有

the conflict-of-interest (COI) committee, responsible conduct of research training, research misconduct investigations, and consultation on other research compliance areas. Agreements typically processed and reviewed by the ORCA include research agreements, confidentiality agreements (also called nondisclosure agreements [NDAs]), proprietary information agreements, intellectual property agreements, secrecy agreements, material transfer agreements, and clinical trial agreements. The ORCA also reviews government and nonprofit research subcontracts.

Compliance with Human Subject Regulations

Background for Human Subject Regulations

On 12 July 1974, the National Research Act (PL 93-348) was signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the responsibilities assigned to the commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines that should be followed to ensure that such research is conducted following those principles. The Belmont Report (1979) is a historical document that summarizes the commission's basic ethical principles (9, 10). Compliance with the three founding principles of the Belmont Report is critical to protecting human subjects participating in either funded or unfunded research: (i) respect (i.e., informed, voluntary consent of subjects), (ii) beneficence (i.e., assessment of the risk/benefit to the subjects), and (iii) justice (i.e., fairness in human subject selection) (9, 10).

Regulatory Requirements for HSPPs

Regulatory requirements defining human subject law can be found in several regulations: (i) Department of Health and Human Services (HHS), 45 CFR 46; (ii) Food and Drug Administration (FDA), 45 CFR 50, 56, 312, 812; (iii) HIPAA, 45 CFR 160,164; and (iv) Family Educational Rights and Privacy Act, 34 CFR 99. Adherence to these regulations is integral to the researcher's ability to perform clinical research.

In these regulations, a "human subject" is a living individual for whom an investigator conducting research collects or obtains data through intervention or interaction with the individual or their private identifiable information. The rights of human subjects are protected by a local HSPP in collaboration with local and national IRBs (10, 11). The HSPP's role is to provide administrative support to the IRB and regulatory expertise to the IRB and investigators. The HSPP also serves as an independent unit where complaints or concerns about clinical research may be reported (12–14). Often, more than one IRB is affiliated with a given HSPP. IRBs may have more than one committee, each typically specializing in either social or biomedical research. Committees review all clinical research applications to evaluate the risks to human subjects participating in the study (10, 11).

HSPPs define research involving human subjects as a systematic investigation (i.e., one having or involving a system, method, or plan), including research development, testing, and evaluation, which are designed to develop, elaborate, expand, or contribute to knowledge that is generalizable to a larger population. The HSPP categorizes the research based on perceived risks to human subjects (10, 15). A clinical researcher must describe the planned study and submit a written or electronic plan to the HSPP before full review by the appropriate IRB committee. Each academic or nonacademic entity engaged in clinical research will have a local HSPP to coordinate the application process.

Human Subject Research: Classifications Based on Risk

There are three classifications of research applications (15): (i) exempt (low or no risk), which receives only an administrative review; (ii) expedited (minimal risk), which is subject to federal regulations and reviewed by the IRB committee chair/cochair or designee; and (iii) full committee (greater than minimal risk), which is subject to federal regulations and requires a review by an IRB committee at a convened meeting. IRB approval of the research plan must be obtained before any subject recruitment, consent, or enrollment is implemented. There is no retroactive approval; data may be lost if permission is not obtained before collection. Any changes to the research protocol must also be submitted for review.

Several types of research studies are not inherently considered human subject research. They are often classified as exempt from IRB review, such as quality improvement activities, diagnostic test development, case studies, program evaluations, secondary analysis of existing data not collected specifically for the proposed project, and other types classified as "unidentifiable." Even if investigators suspect that the project will not likely be classified as human subject research, they must submit it to the HSPP for review. Typical exempt applications include those for research studies involving the following activities: standard educational practices; tests, surveys, interviews, and some observations; collection or analysis of existing data that cannot be linked to a subject; public benefit or service programs (e.g., Medicare); and taste and food evaluation studies. In some particular circumstances, identifiable subjects are accepted; however, these exceptions are rare.

In 45 CFR 46.102.i, a study with "expedited minimal risk" is described as research in which "the probability and magnitude of harm or discomfort anticipated in the

本书版权归John Wiley & Sons Inc.所有

research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Studies performed in diagnostic laboratories that use "remnant" or "discard" specimens are often placed in this category.

In contrast, "full committee" projects include all other projects. After review by the HSPP, these projects may be approved by the IRB under the following regulatory criteria (45 CFR 26.111). Researchers must ensure that:

- The risks to subjects are minimized.
- The risks are reasonable, considering the anticipated benefits.
- The selection of the subjects is equitable.
- Informed consent will be sought.
- Informed consent will be appropriately documented.
- There are adequate provisions for data monitoring.
- There are sufficient provisions to protect subjects' privacy and maintain data confidentiality.

Human Subject Training Requirements and Site Authorization

To become eligible to apply to the HSPP or to participate in human research projects, collaborative IRB initiative (CITI) training is required for investigators and staff involved in the research. Training is valid for 4 years, after which time retraining must occur. After completing CITI training, a verification-of-training form must be submitted to the HSPP.

When research is performed outside the PI's home department, e.g., when an academic researcher requires access to subjects or clinical samples from a hospital, a written document, called a site authorization, is required. The site authorization letter must contain signatures that document site review and must be submitted to the HSPP. The site authorization document ensures that the site is aware of and accepts collaboration in the research project.

Informed Consent

The human subject consenting process is detailed for projects categorized for full IRB review, and compliance with HSPP protocol is critical. Several types of consent (subject consent, parental permission, minor assent, and subject disclosure) are defined. They are meant to fully inform the subjects of everything they will experience because of the study and everything they will receive from the research study. A consent form is required and should include a thorough, clear description of the research goal, sufficient detail about the study procedures, and answers to all questions on the HSPP project approval form (PAF), which may vary slightly by organization. If PAF questions do not apply to the study, the investigator must document why they are not applicable. All recruitment materials, written consents, oral scripts, and other recruitment information must be written at a 6th- to 8th-grade reading level. Written materials must be clear and concise and not include language that may place coercion or undue influence on a subject to participate. Special provisions, such as a witness, a third party, or a test of knowledge, are expected for specific populations (e.g., children, the cognitively impaired, those under extreme duress, other vulnerable or special populations, etc.).

When subject recruitment is performed outside the PI's department, a written site authorization is also required and is maintained in the PI's files. All recruitment methods and recruitment materials must be IRB approved before use (e.g., flyers, handouts, emails, and scripts). Posting a flyer or brochure or using a facility to identify potential subjects is considered offsite recruitment and requires site authorization. Materials must be clear and concise and not include language that may place coercion or undue influence on a subject to participate. Specific dollar amounts or awards for participation in the research are not allowed to be listed in recruitment materials; it is acceptable to state that "compensation will be provided."

Sometimes, a waiver of consent or documentation of informed consent (signature requirement) is available, for example, if research is performed in emergency departments under life-saving circumstances when there is no time to obtain informed consent and the patient is unlikely to survive without intervention. Any changes in the consent form must be resubmitted for approval by the IRB before use, documenting changes with a version date and line numbers on the document to help track changes.

Special Populations

Special populations are those identified in regulations as vulnerable and may require additional protections. They include minors (<18 years of age), pregnant women or their fetuses, prisoners, cognitively impaired and economically disadvantaged individuals, educationally disadvantaged individuals, students, and employees. In addition, each state may have policies and laws related to tribal nations. Native American nations have the legal right to:

- Approve or deny requests for research.
- Halt research activities without disclosing their reasons.
- Decide whether the outcomes of research activities conducted within their jurisdiction will be disclosed or disseminated (or not) in oral or written form.
- Negotiate exclusive or shared ownership of research data.
- Require consultation by American Indian Studies (social and behavioral) and Office for Multicultural Affairs (biomedical).

本书版权归John Wiley & Sons Inc.所有

- Include the use of secondary data that were not collected by the PI of the proposed project, even if the data are deidentified.

Tribal authorization is generally required before conducting research.

Continuing Review by the IRB

Nonexempt projects must be reapproved by the IRB each year before expiration. If the project is not approved by the expiration date, the project is administratively closed, and a new application will be required. Investigators are restricted from submitting new human research until the completed continuing review form has been received and approved. If data for a project are no longer required, the project can be concluded and closed. However, if a PI leaves an institution, the PI is responsible for transferring oversight or completing the project before leaving the institution.

Record Retention for HSPPs

While requirements in each state vary per the local record retention and disposition schedule, the PI maintains human research records, including signed and dated consent documents.

Compliance with HIPAA

Also referred to as the Kennedy-Kassebaum Act, the Health Insurance Portability and Accountability Act of 1996 (PL 104-191; HIPAA) was enacted by the federal government on 21 August 1996, with the intent to ensure health insurance portability, reduce healthcare fraud and abuse, guarantee security and privacy of health information, and enforce standards for health information (16). HIPAA was created to establish minimum federal standards for safeguarding the confidentiality of individually identifiable health information. The regulation has three areas of focus: (i) portability of and access to health benefits, (ii) prevention of fraud and abuse, and (iii) administrative simplification. HIPAA expands the False Claims Act to define healthcare claims with intentional fraud as a criminal act.

The term "HIPAA privacy" refers to accessing and sharing a patient's data and protected health information (PHI), i.e., the information that identifies an individual and relates to the person's physical or mental health or condition, the provision of healthcare to that person, or payment for the provision of healthcare to that person. In essence, PHI is any information transmitted or maintained in any form, such as prescription records, patient profiles, and oral communications on the phone or during patient counseling. Confidentiality practices for PHI limit who can access the data, define how they will be stored, and ensure individuals' access to their PHI. Compliance with the rule involves the implementation of policies and procedures to ensure the confidential use and disclosure of PHI by all staff. Standard personal identifiers that cannot be shared without prior permission include:

- Names
- Geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and equivalent geocodes, except for the initial five digits of a ZIP code
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death, and all ages over 89
- Telephone numbers and fax numbers
- Email addresses
- Social security numbers and medical record numbers
- Health plan beneficiary numbers
- Account, certificate, and license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web universal resource locators (URLs)
- Biometric identifiers, including fingerprints and voice prints
- Full-face photographic images and any comparable images
- Internet protocol address numbers
- Any other unique identifying number, characteristic, or code

According to 45 CFR 164.530(c), standard information security safeguards must encompass appropriate administrative, technical, and physical safeguards to protect the privacy of PHI. Entities must "reasonably" safeguard PHI from intentional or unintentional uses or disclosures in violation of the standards and must "reasonably" safeguard PHI from incidental uses or disclosures that result from a permitted or required use or disclosure. Organizations must protect the confidentiality and security of health information as it is used, disclosed, and electronically transmitted and create a framework using standardized formats for sending electronic health information more efficiently.

Multiple users may access health information when related to patient care. For healthcare workers, access is limited to persons or classes of persons who require access to PHI to carry out their healthcare duties. Disclosure of PHI is limited to the minimum amount necessary to

本书版权归John Wiley & Sons Inc.所有

accomplish the intended purpose of the authorized use, disclosure, or request. Organizations must make reasonable efforts to restrict access. It is the right of an individual to request restrictions on the uses and disclosures of PHI and permit an individual to request confidential communication of PHI at alternative locations or by alternative means.

Researchers may access PHI with approval from the HSPP. One approach is the deidentification of the subject's samples. Deidentified PHI, which removes identifiers of the individual or their relatives, employers, or household members, is commonly thought to limit the disclosure to the minimum amount necessary to accomplish the intended purpose of the authorized disclosure.

An aspect of HIPAA, the Administrative Simplification Rule, addresses electronic data interchange (EDI)/transmission, privacy, security, and unique identifiers. Electronic transmission of healthcare data is most commonly used for claims processing and payment, reduction of paper transactions, reduction of the risk of lost paper documents, and referrals and enrollment. The privacy aspect of EDI requires covered entities (e.g., healthcare providers, healthcare plans, and healthcare clearinghouses) to safeguard patient healthcare information. Security is comprehensive and coordinated and applies to all aspects of data security. An intricate interaction of all factors of information systems is required to ensure data protection such that the information system will be scalable for all sizes of covered entities. The information system should be technology-agnostic and ensure compliance by the workforce. The HIPAA Breach Notification Rule, 45 CFR §§ 164.400-414, requires HIPAA-covered entities and their business associates to provide notification following a breach of unsecured PHI. A breach is defined as an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of the PHI, with a moderate to high probability that:

1. The nature and extent of the PHI include protected types of identifiers and the likelihood of reidentification.
2. An unauthorized person to whom the disclosure was made used the PHI.
3. The PHI was acquired or viewed.
4. The risk to the PHI was unmitigated.

The Centers for Medicare and Medicaid Services (CMS) must conduct audits for organizations with PHI policies. Penalties for HIPAA violations include fines or imprisonment. Civil monetary penalties are tiered based on knowledge from the audits, and penalties can reach $1.5 million annually. Imprisonment for up to 10 years may result from knowingly misusing individually identifiable health information.

Compliance with Conflict-of-Interest Policies

A COI is a situation in which there are conflicting incentives with identified potential for injecting inappropriate considerations into a given decision or evaluation—a possibility to compromise or jeopardize the integrity or the credibility of a study's results (17–21).

A COI can be described as a set of conditions where professional judgment has the potential to be biased by either financial or nonfinancial secondary interests of a clinical practitioner or research investigator (22). A COI is not an outcome but a situation, a confluence of potentially competing factors. It is not in and of itself a measure of character or integrity. Still, it has potential effects that may operate consciously or unconsciously, which must be addressed to maintain integrity and credibility in clinical practice and research.

In organizations, it is the potential for COI that needs to be managed to maintain integrity and credibility. Identified COIs are often financial because they are more readily measurable than other conflicting incentives; however, nonfinancial COIs are equally important. For example, careers, lives, personal relationships, and institutions with multiple facets will have these perceived conflicts whenever intersections of potentially competing interests exist. Scientific evidence supports our concerns about subconscious COI influences (https://www.aamc.org/what-we-do/mission-areas/medical-research/conflicts-of-interest/financial-disclosures-biomedical-journals, accessed 18 September 2023).

Disclosure of COI is essential, both to individuals and to their organizations. In literature reviews, nondisclosure was noted to occur in clinical practice guidelines across various clinical disciplines; however, there is little evidence to characterize the effects on clinical recommendations (20). Attention to COI issues is longstanding, sometimes driven by corporate sponsorship of clinical trials in the pharmaceutical industry (23). A growing number of publishers have COI policies, including some in pathology and laboratory medicine (18), while some include them in the instructions to authors.

Some potential poor outcomes in COI situations include the following: avoidable injury to human research subjects, compromised research allocations, and damage to research credibility and institutional credibility with external stakeholders. Most organizations have a policy and review procedure for COI related to research and practice, as it is a requirement for organizations that receive federal research funding, for research involving FDA approval, and for accreditation by the Association for Accreditation of Human Research Protection Program. Many organizations have similar policies for clinical practice and purchasing. An organization's COI policy protects the integrity and

本书版权归John Wiley & Sons Inc.所有

credibility of research and related teaching, public service, and business operations. It includes an institutional policy for disclosure of COI and review and oversight of personal financial interests related to the research.

The COI policies apply to all faculty, staff, and students (including full-time and part-time faculty and staff, visiting faculty, postdoctoral scholars, undergraduates, graduate students, postdoctoral fellows, and all research team members) who are in a position to commit organizational resources or to influence such decisions. Anyone who can impact decision making or offer advice on purchasing, hiring, or anything involving corporate funds or facilities must file COI statements. Research team members who need to file COI documents include the principal investigator and any other person responsible for research design, conduct, or reporting.

The critical components of a COI policy and process include identifying the potential conflicts and the intersection of a personal financial interest with a transaction for which the individual has evaluation/decisional authority. In addition, review, assessment, and decision processes regarding the identified COIs should detail the composition of a review panel and criteria for COI review. The review panel assesses the relationship between the transaction and the potential for change in the value of the financial interest.

COI management strategies include disclosure in all research presentations, the performance of interaction with human subjects by a different qualified researcher who is not subordinate to the PI, use of an independent data monitoring system, independent supervision of potentially vulnerable subordinate researchers (trainees, students, or junior faculty), change in PI, or divestiture. Perceived or potential COIs exist in situations where an individual member of the organization, a member of the individual's family, or another individual with a close personal relationship has financial interests, personal relationships, or professional associations with an outside individual or organization, such that the activities within the organization could appear to be biased against the organization by that interest or relationship. An actual COI arises when financial or other personal or professional considerations compromise an individual's objectivity, professional judgment, professional integrity, and ability to perform their responsibilities. A COI disclosure form should be completed as soon as the situation arises and before the activity is begun. A COI disclosure survey is typically conducted annually.

The concepts of conflict of interest and commitment arise from the fiduciary duty that employees owe to their employer. When we make decisions as employees, we must make those decisions with the corporate interest of our employer as our guide. When an outside interest or commitment prevents us from doing the job we have accepted or from using only our organization's interest in guiding our decisions as employees, there is a conflict of interest or commitment. There are two common avenues for identifying potential COI related to sponsored research and technology transfer: (i) during the processing of a sponsored project agreement, the PI will determine whether they, a key investigator, or any family member of these individuals has a financial or management interest in the project sponsor or some other entity related to the project, and (ii) during the disclosure of an invention and the development of subsequent technology transfer agreements, it is determined that the inventor(s) or their family members have a financial or management interest in a company the organization may wish to work with on the invention's development, manufacturing, or marketing.

If a conflict is deemed to exist, the committee designs a plan to manage the specific conflict situation. An appropriate management plan must be in place before organizations accept any sponsored award or technology transfer agreement in which a financial or management conflict is judged to exist. The relevant COI review committee will monitor any management plans and require updates of disclosures from individuals involved in those management plans at least annually.

A COI policy also provides guidelines for employees interacting with companies through consulting agreements, the formation of spin-off companies, and research agreements with companies in which faculty members have significant equity positions or financial interests. Department heads are typically responsible for ensuring compliance with the COI policy. Any potential COI must be reviewed by the institutional review committee (IRC), and any intellectual property commitment receives special attention.

Intellectual Property Considerations

Policies relating to intellectual property encourage employees to engage in creative endeavors and recognize the intellectual property as one tool organizations may use to disseminate new knowledge thus created (3). The policy generally specifies the categories of intellectual property that fall under the policy, describes factors that determine intellectual property ownership, lists the administrative responsibilities of the organization and its employees who create intellectual property, describes the interaction between publication rights and the protection of intellectual property, specifies that revenue from the commercialization is shared with those who created the intellectual property, and provides guidelines for faculty-owned companies regarding conflict of interest. An organization's intellectual property policy also sets criteria for the ownership and use of the organization-owned intellectual property. It defines procedures to manage intellectual property at the organization (3).

本书版权归John Wiley & Sons Inc.所有

GLP and GCP Regulations

Last revised in 2016, good clinical practices guidelines (GCPs) encompass all aspects of clinical trials involving human subjects, elements of which are detailed throughout this chapter (24).

GCPs present regulations for the sponsor of the research as well as the study directors. Principles of GCP involve ethical aspects of research, including risks and benefits to the human subjects; protection of human subjects; informed consent; confidentiality; the quality of science employed, including the investigational product to be studied; the science of the protocols used; quality assurance practices such as compliance with protocols; and data handling, including data acquisition, documentation of data, record keeping, correspondence, data analysis and monitoring, and data and document storage. Clinical and laboratory data used in national regulatory decisions must meet the written specifications detailed under the GCP regulations. Adverse-event reporting is also an aspect of GCP.

Sponsor Responsibilities

A sponsor is usually a pharmaceutical or biotechnology company. The sponsor is an individual, company, institution, or organization responsible for initiating, managing, and financing a clinical trial (24). A sponsor's duties include developing the study protocol and study case report forms, which are printed or electronic documents designed to record all related information to be reported to the sponsor on each trial subject or sample. The sponsor is also responsible for selecting qualified investigators and study directors and providing them with investigational articles, reagents, and instruments. Sponsors must provide training sessions for study personnel, maintain records, and ensure adherence to research protocols by performing regular monitoring and data and compliance audits. Finally, sponsors must inform the FDA and investigators of safety information and adverse events and submit preliminary and final reports to the FDA and other regulatory agencies.

Study Director Responsibilities

The study director is the PI on submitted sponsored projects' research and research contracts (24). A study director may appoint a GCP manager for operational issues. However, the study director is still responsible for the conduct, interpretation, analysis, documentation, and reporting of the results of the GCP study. The study director may advise or write protocols and submit the protocol for IRB review. The study director obtains a quality assurance office (QAO) signature for the proposal's routing sheet (a form most organizations use to document that all relevant parties and departments are aware of and agree to participate in the project and the project budget). The study director also ensures that all personnel have a copy of the protocol and standard operating procedures (SOPs). Examples of additional duties of the study director include:

- Ensuring that the signature/initial log is completed for the study
- Providing a study calendar of study phases/study activities to the QAO
- Reviewing raw data and records
- Ensuring that unforeseen circumstances are documented and reviewed by the QAO
- Responding in writing to written QAO inspection/audit reports
- Preparing and signing the final report after review by the QAO
- Ensuring that study materials are placed in departmental archives or the organization's records management and archives department
- Reporting safety information to the institutional IRB and the sponsor

Quality Assurance Office: Organization, SOPs, Inspections, and Reporting Data

The quality assurance department of an organization works with students, staff, and faculty to ensure that all research is compliant with federal regulations guiding GCPs for studies supporting applications related to the U.S. FDA for medical devices for human use. The QAO is typically wholly independent of any federal or sponsor funding. It is found within the organization's department responsible for all safety and regulatory compliance. Examples of QAO oversight include:

- Review of the study and SOPs before the study is initiated
- Coordination of protocol discussions with study personnel
- Inspection of equipment maintenance and calibration records before the study is initiated
- Monitoring at random intervals throughout the study
- Coordination of regulatory inspections and recording of all inspection report data and any corrective action
- Ensuring that QAO checklists for all inspections during the study are filed under the study number in the QAO
- Ensuring that the study name, inspection dates, and phase of the study inspected by the QAO are available for inspection by regulatory inspectors
- Ensuring that all records and checklists are archived at the end of the study (state and federal laws mandate what the organization does with its records and how long they are retained)

本书版权归John Wiley & Sons Inc.所有

GLP Background

Good laboratory practice (GLP) is a system of management controls for nonclinical research laboratories and organizations. GLP ensures research uniformity, consistency, reliability, reproducibility, quality, and integrity (25, 26). GLP applies to nonclinical studies conducted for the assessment of the safety or efficacy of chemicals (including pharmaceuticals) for humans, animals, and the environment and is not required for clinical trials involving human subjects; however, GLP regulations define standardized practices that are aimed at ensuring reproducibility of results and are valuable to any professional scientist by providing practices for the processes, organization, and conditions under which laboratory studies are conducted (24).

The applicability of traditional GLPs to analytical methods and instrument assessment supports their usefulness for all scientific disciplines regulated by the FDA (24). An internationally recognized definition of good clinical laboratory practices (GCLPs) can be found on the World Health Organization iris website (27). GCLPs are often helpful for clinical laboratories during clinical trials for *in vitro* diagnostics devices and laboratory methods whose analytical results will be submitted to the FDA for review. In many cases, GCLP quality assurance practices provide a practical way to deal with the large quantities of data, documents, and operating procedures required for participation in clinical trials for *in vitro* diagnostics.

The original GLP regulatory mandate was promulgated in 1978 by the FDA and published in the *Federal Register* (43 FR 59985-60020) (25). It was followed a few years later by the U.S. Environmental Protection Agency document, as outlined in the Organization for Economic Cooperation and Development principles of GLP in 1992. GLP is, in essence, a data quality system and should not be confused with standards for laboratory safety or practice or Clinical Laboratory Improvement Act guidelines for laboratories. GLP defines responsibilities for investigators and appropriate practices and safeguards for research activity. Although GLP is not required for clinical trial participation, it covers many areas. Several, which are crucial to good scientific practices and are the underpinning of successful clinical trial laboratories, are described in the following sections (24, 26).

Equipment and Validation of Equipment

SOPs are required for the equipment specified in the protocol (25). The equipment name and identification are entered on the GLP study checklist for each phase of the study. Standards are defined for the inspection, cleaning, calibration, and maintenance of equipment specific to the study, and they are discussed with the staff for specific use during the study. The QAO reviews equipment SOPs and calibration records before the investigation is initiated.

Standard Operating Procedures

SOPs are the underpinnings and foundation of any GLP study (25). Besides equipment, SOPs are required for tests, controls, and any process policy or procedure. Study SOPs are reviewed by the QAO and are included in the protocol. They are distributed to all personnel on the GLP study and filed in a binder in the study manager's office.

Reagents and Solutions for Tests and Controls

Reagents and solutions are under the purview of GLP regulations (25). Pharmaceutical-grade compounds and drugs are within the expiration date and recorded on the GLP study checklist. Solutions for cell culture are prepared and used according to SOPs and recorded on the checklist; any solution's formulation is recorded and dated on the GLP checklist.

Final Research Reports

The final research report is scrutinized and reviewed, with attention given to the raw data from which conclusions were drawn (25). The QAO reviews the final report for all phases of the study. The raw data are reviewed to verify that the study director's data charts and tables are derived from the raw data. The QAO inspections and review dates are written in the quality assurance statement, which is given to the study director for inclusion in the final report.

SUMMARY

The clinical research compliance program aims to promote operational excellence, best practices, and regulatory compliance in clinical research conducted within an organization. The compliance program promotes research activities by supporting the clinical trial's administrative process. It creates a culture of ethics, integrity, and compliance with applicable laws, regulations, and organizational policies. It also provides educational opportunities to research staff and enhances the exposure and opportunities for the organization's clinical trial capabilities.

KEY POINTS

- Human subject protection laws are designed to protect research subjects from harm.
- The Health Insurance Portability and Accountability Act (HIPAA) protects the privacy of healthcare records and personal information.
- Conflict-of-interest policies are designed to mitigate biases that could occur when researchers invest financially in companies that sponsor clinical research.
- Good laboratory practices (GLPs) are designed to maximize the accuracy of research results.

本书版权归John Wiley & Sons Inc.所有

GLOSSARY

See also the following link for more information: http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (accessed 18 September 2023).

CMS Centers for Medicare and Medicaid Services.

COI Conflict of interest. An organization's COI policy/committee protects the integrity and credibility of research and related teaching, public service, and business operations. It includes an institutional policy for disclosure of COI and review and oversight of personal financial interests related to the research.

GCP Good clinical practices. GCP encompass all aspects of clinical trials involving human subjects.

GLP Good laboratory practice. GLP is a system of management controls for nonclinical research laboratories and organizations. GLP ensures research uniformity, consistency, reliability, reproducibility, quality, and integrity. In many cases, GLP quality assurance practices provide a practical way to deal with the large quantities of data, documents, and operating procedures required for participation in clinical trials for in vitro diagnostics.

HIPAA Health Insurance Portability and Accountability Act. This act was created to establish minimum federal standards for safeguarding the confidentiality of individually identifiable health information. The regulation has three areas of focus: (i) portability of and access to health benefits, (ii) prevention of fraud and abuse, and (iii) administrative simplification.

HSPP Human subject protection program. The HSPP categorizes research based on perceived risks to human subjects. A clinical researcher must describe the planned study and submit a written or electronic plan to the HSPP before full review by the appropriate IRB committee.

IACUC Institutional animal care and use committee.

Informed consent The human subject consenting process is detailed for projects categorized for full IRB review, and compliance with HSPP protocol is critical. Several types of consent (subject consent, parental permission, minor assent, and subject disclosure) are defined.

IRB Institutional review board.

ORCA Office of research and contract analysis. The ORCA is an administrative resource to ensure that organizations conduct their educational, research, and business processes in a manner that is consistent with regulatory, statutory, and organization requirements.

OSP Office of sponsored projects. The OSP serves to review, negotiate, and approve terms and conditions for grants and cooperative agreements. The OSP also supports faculty and staff throughout the award life cycle, from application to closeout.

PI Principal investigator. The PI is the person in charge of a clinical trial or a scientific research grant. The PI may also be referred to as the project director.

QAO Quality assurance office. The QAO of an organization is typically wholly independent of any federal or sponsor funding. It is found within the organization's department responsible for all safety and regulatory compliance.

SOP Standard operating procedure. Besides equipment, SOPs are required for tests, controls, and any process policy or procedure. Study SOPs are reviewed by the QAO and are included in the study protocol.

Sponsor A sponsor is usually a pharmaceutical or biotechnology company. The sponsor is an individual, company, institution, or organization responsible for initiating, managing, and financing a clinical trial.

REFERENCES

1. **Biaggioni I.** 2017. Industry-sponsored clinical research in academia, p 671–677. *In* David R, Gordon HW (ed), *Clinical and Translational Science*. Elsevier, London, United Kingdom.

2. **Califf RM**. 2017. Clinical trials, p 25–50. *In* David R, Gordon HW (ed), *Clinical and Translational Science*. Elsevier, London, United Kingdom.

3. **Basu S.** 2017. Translating science to the bedside: the innovation pipeline, p 399–421. *In* David R, Gordon HW (ed), *Clinical and Translational Science*. Elsevier, London, United Kingdom.

4. **Hartmann KE**, **Heitman E**, **Brown NJ**. 2017. Education, training and career choices: training basic, clinical and translational investigators, p 637–647. *In* David R, Gordon HW (ed), *Clinical and Translational Science*. Elsevier, London, United Kingdom.

5. **Nguyen C**, **Gassman A**, **Joffe HV**. 2017. Regulatory environment, p 423–438. *In* David R, Gordon HW (ed), *Clinical and Translational Science*. Elsevier, London, United Kingdom.

6. **Robertson D**, **Williams GH**. 2017. Clinical and translational science infrastructure, p 620–632. *In* David R, Gordon HW (ed), *Clinical and Translational Science*. Elsevier, London, United Kingdom.

7. **Schwartz JS**. 2017. Health services research: translating discovery and research into practice and policy, p 112–132. *In* David R, Gordon HW (ed), *Clinical and Translational Science*. Elsevier, London, United Kingdom.

8. **Vermund SH**, **Karim QA**. 2017. Governmental support of research, p 679–715. *In* David R, Gordon HW (ed), *Clinical and Translational Science*. Elsevier, London, United Kingdom.

9. **Federal Register**. 1979. Protection of human subjects; Belmont Report: notice of report for public comment. *Fed Regist* **44**:23191–23197.

10. **Koski G.** 2017. Ethical issues in translational research and clinical investigation, p 415–426. *In* David R, Gordon HW (ed), *Clinical and Translational Science*. Elsevier, London, United Kingdom.

11. **Rice TW**. 2008. The historical, ethical, and legal background of human-subjects research. *Respir Care* **53**:1325–1329.

12. **Emanuel EJ**, **Wendler D**, **Grady C**. 2000. What makes clinical research ethical? *JAMA* **283**:2701–2711.

13. **Federal Register**. 2001. Protection of human research subjects. Final rule. *Fed Regist* **66**:56775–56780.

14. **Greco D**, **Diniz NM**. 2008. Conflicts of interest in research involving human beings. *J Int Bioethique* **19**:143–154, 202–203.

本书版权归John Wiley & Sons Inc.所有

15. Federal Register. 1998. Protection of human subjects: categories of research that may be reviewed by the Institutional Review Board (IRB) through an expedited review procedure—FDA. Notice. *Fed Regist* **63**(Pt 1):60353–60356.

16. Gunter KP. 2002. The HIPAA privacy rule: practical advice for academic and research institutions. *Healthc Financ Manage* **56**:50–54.

17. Ackerman AB. 2005. Reviewer conflicts of interest should be disclosed. *J Am Acad Dermatol* **52**:538–539.

18. Hall PA, **Poulsom R**, **Wixon J**. 2009. How does *The Journal of Pathology* deal with conflict of interest? *J Pathol* **219**:396–399.

19. Morin K, **Rakatansky H**, **Riddick FA Jr**, **Morse LJ**, **O'Bannon JM III**, **Goldrich MS**, **Ray P**, **Weiss M**, **Sade RM**, **Spillman MA**. 2002. Managing conflicts of interest in the conduct of clinical trials. *JAMA* **287**:78–84.

20. Norris SL, **Holmer HK**, **Ogden LA**, **Burda BU**. 2011. Conflict of interest in clinical practice guideline development: a systematic review. *PLoS One* **6**:e25153.

21. Rabinovitch A. 2004. Financial conflict of interest? *Arch Pathol Lab Med* **128**:1328, discussion 1328.

22. Thompson DF. 1993. Understanding financial conflicts of interest. *N Engl J Med* **329**:573–576.

23. Schwarz RP Jr. 1991. Maintaining integrity and credibility in industry-sponsored clinical research. *Control Clin Trials* **12**:753–760.

24. Zgheib NK, **Tomasic SL**, **Branch RA**. 2017. Good clinical practice and good laboratory practice, p 261–278. *In* David R, Gordon HW (ed), *Clinical and Translational Science*. Elsevier, London, United Kingdom.

25. Federal Register. 1978. Nonclinical laboratory studies: good laboratory practice regulations. *Fed Regist* **43**:59985–60025.

26. Macleod MR, **Fisher M**, **O'Collins V**, **Sena ES**, **Dirnagl U**, **Bath PM**, **Buchan A**, **van der Worp HB**, **Traystman RJ**, **Minematsu K**, **Donnan GA**, **Howells DW**. 2009. Reprint: Good laboratory practice: preventing introduction of bias at the bench. *J Cereb Blood Flow Metab* **29**:221–223.

27. UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases. 2009. Good clinical laboratory practice (GCLP). World Health Organization. https://iris.who.int/handle/10665/44092. Accessed 18 September 2023.

APPENDIX 41.1 Useful Websites

CITI Program
https://about.citiprogram.org (accessed 8 February 2023)

The Common Rule
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (accessed 8 February 2023)

Food and Drug Administration (FDA)
www.fda.gov (accessed 8 February 2023)
https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/good-clinical-practice (accessed 8 February 2023)

Environmental Protection Agency
www.epa.gov (accessed 8 February 2023)

International Organization for Standardization
www.iso.org (accessed 8 February 2023)

Office for Human Research Protections (OHRP)
http://www.hhs.gov/ohrp (accessed 8 February 2023)

U.S. Department of Health and Human Services
http://www.hhs.gov (accessed 8 February 2023)

本书版权归John Wiley & Sons Inc.所有

42

Introduction
Types of Research Studies
Observational Studies • Mechanistic Studies • Therapeutic Studies • Large-Scale Clinical Trials • Meta-Analyses and Systematic Reviews
Translational Research
Sequence of Investigation
Study Design • Hypothesis Generation • Sampling the Population • Deciding on Sample Size, Measurements, and Endpoints • Feasibility • Confounding Variables and Bias • Human Subject Protection • Collecting and Storing Data • Data Analysis and Conclusion Formulation
Traditional Biostatistics
Descriptive Statistics • Inferential Statistics: Issues for Medical Devices • Challenges for Diagnostic Studies
Other Research Considerations
Systematic Reviews and Laboratory Medicine Best Practices
Evidence-Based Laboratory Medicine • Laboratory Medicine Best Practices Initiative
Using Machine Learning for Prediction
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES
APPENDIXES

Clinical Trials and Evidence-Based Research in the Clinical Laboratory

Donna M. Wolk and Natalie N. Whitfield

OBJECTIVES

To acquaint the clinical laboratory with the basic types of experimental approaches used by clinical (patient-oriented) researchers

To define the basic terms typically used in clinical research

To describe the concept of a systematic review of the literature

To describe initiatives occurring for evidence-based laboratory medicine

To review applications of machine learning for laboratory medicine

We are what we continually do; excellence then is not an act but a habit.

ARISTOTLE

LABORATORY INTERVENTIONS ARE OPTIMALLY known to be data driven, outcome oriented, and evidence based. Therefore, laboratory professionals need background in experimental study design and biostatistical methods so that laboratory data can be used to generate outcome data from quality improvement activities and comparative analytics of new testing methods.

In vitro diagnostic (IVD) clinical research studies utilizing human tissues or fluids, which cannot be linked long-term to a living individual, are common in many clinical laboratories. Clinical IVD research differs from what is defined as patient-oriented research (POR), which is commonly interventional, may occur in collaboration with clinical laboratories, and is defined as "research conducted with human subjects" (or on material of human origin, such as tissues, specimens, and cognitive phenomena) for which an investigator directly interacts with human subjects, who have consented to the study (1).

Several types of POR are found in academic and non-university-based healthcare systems. They are diverse in scope and include (i) mechanistic (physiological) studies of human disease involving the detailed investigation of a biological process, (ii) therapeutic studies that focus on treatment designed to improve a disease or condition, and (iii) clinical trials, which are most often extensive, definitive studies, from which data are submitted to the U.S. Food and Drug Administration (FDA) for review when new drugs, technologies, and devices are planned (1).

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch42.

本书版权归John Wiley & Sons Inc.所有

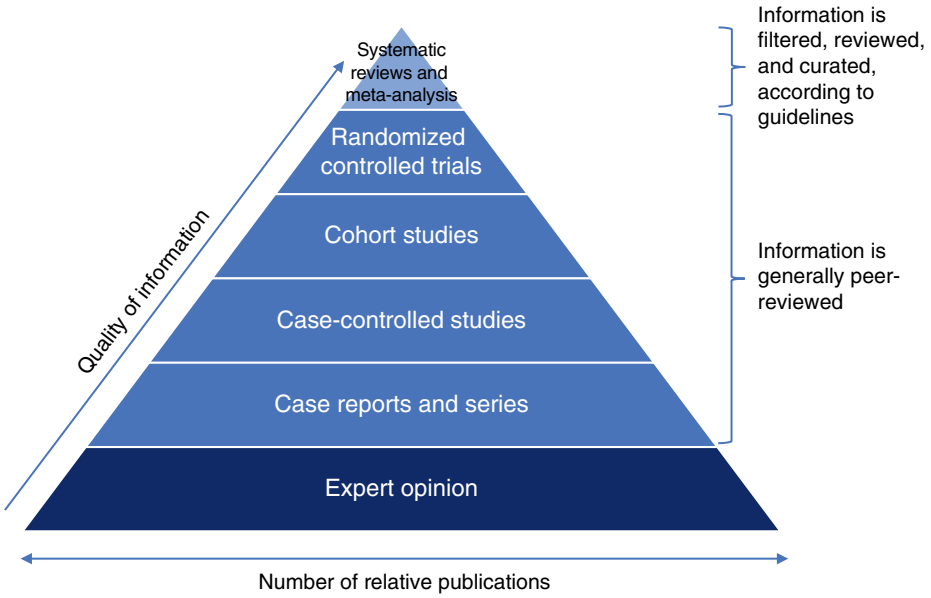


Figure 42.1 Hierarchy of evidence.

In any clinical study, formulating a sound and reasonable hypothesis is always the starting point, followed by appropriate and ethical study design, choice of relevant endpoints, statistical analysis, feasibility analysis, and hypothesis testing (1). A glossary of commonly used clinical research terms can be found at the end of this chapter. Figure 42.1 depicts the typical hierarchy of evidence for study and publication types.

Types of Research Studies

Observational Studies

Observational studies involve humans (cohort or epidemiological studies) but are not categorized explicitly as POR. Instead, they include recruiting patients (human subjects) and are often critical to hypothesis generation and subsequent interventional studies. Observations generally relate to a public health concern or biological principle. Observational studies are primarily descriptive and often lead to the determination of data associations. The goals of these studies are to obtain data and determine an association, and they typically do not have well-defined mechanistic hypotheses. Observational studies are generally large population-based studies that collect detailed data on clinically relevant endpoints and are considered rigorous in design (1). Such studies are not definitive or causative, since confounding phenomena can occur (2, 3). These studies are considered hypothesis generating rather than hypothesis testing. Analyses may be performed to control for confounders, e.g., in multivariate regression, but causality can be only inferred, not proven (2, 3). For example, human genome studies are a type of observational study. They may show an association between a particular genotype and disease. They may also help determine the efficacy of specific therapy in pharmacogenomic analysis.

Mechanistic Studies

In contrast to observational studies, mechanistic studies are used to determine causality. Such studies are hypothesis driven, and formulation of the hypothesis is the critical element for the study's success. These studies are commonly smaller and determine disease physiology or mechanism. They define detailed endpoints assessed in response to a relevant intervention or a disruption of biological function. Because they use novel endpoints to evaluate complex physiology, small mechanistic studies may not be generalizable to large populations and may have less clinical relevance than large-scale trials, but they are essential in stimulating more extensive therapeutic studies.

Therapeutic Studies

Therapeutic studies determine the efficacy of a medicine or a treatment designed to improve a condition or disease. These are often smaller, more preliminary, and less generalizable than clinical trials but involve some of the same design issues. For example, when a new drug is tested in humans, phase I studies are for safety, phase II studies are the first therapeutic trials, and phase III studies are commonly more extensive clinical trials. Clinical trials are one form of a therapeutic study. Therapeutic studies are generalizable only to the conditions of the study and the patients in the study. They are usually less likely to assess hard endpoints and tend to be less definitive than large-scale clinical trials. Nevertheless, they are critical to determining a drug's risk-benefit ratio, which can be further explored in large-scale trials (1).

本书版权归John Wiley & Sons Inc.所有

Large-Scale Clinical Trials

Most large-scale clinical trials are randomized controlled trials (RCTs) and are placebo controlled to minimize confounding. RCTs may take a long time to complete and are costly. Still, they are necessary to definitively prove the effectiveness of new treatment strategies, define new interventional approaches, and confirm the proof for existing practices in clinical medicine. Because such studies are often multicenter, endpoints must be identical for all sites. Stratification and analyses of pooled data and data from each site ensure that potential confounding variables are spread equally across the data groups (1).

Clinical trials are always hypothesis driven and need to be adequately powered, i.e., large enough to ensure that a negative result is not the result of insufficient samples or patients but an actual biological result or diagnostic condition. Even these studies can be generalized only to the specific population and intervention studied and may be misinterpreted or overgeneralized. Large clinical trials are often more critical in determining the clinical efficacy of a drug than elucidating mechanisms. It is a requirement to register all clinical trials, and they can be searched in a database, like www.clinicaltrials.gov (accessed 29 December 2022).

Meta-Analyses and Systematic Reviews

A meta-analysis is the process by which the results of multiple individual studies are statistically combined (4–7). See "Systematic Reviews and Laboratory Medicine Best Practices" later in this chapter for more information.

Translational Research

Translational research explores the transition of basic research practices and findings to day-to-day use in a clinical setting, such as the clinical laboratory. The National Institutes of Health developed Clinical and Translational Science Awards to focus efforts and provide resources on translational research. Although the phrase "bench to bedside" is a colloquial description of this process, translational research is not unidirectional. Once a biological tenet is adapted to a medical setting, clinical data from patients may inform both patient-oriented and basic investigations. An example of this process is the discovery of procalcitonin (PCT) and its relationship to bacterial infections, leading to the use of PCT as an indicator of disease or of successful antimicrobial therapy (8–10).

More common in laboratory settings, a second translational step is receiving consideration, which is the translation of research findings from POR and clinical trials into daily clinical practice. Thus, POR plays a central role in translating basic research findings, clinical trial data, and other innovations to improve medical practice and patient care (1). An example of how diagnostic clinical trial data may enhance our understanding of infections, multiplex molecular panel testing identified an increased frequency of coinfections that spawned investigations to detail the clinical impact of coinfections on disease severity.

Sequence of Investigation

The sequence of POR involves observation, generation of a testable hypothesis, the design of a study that will test this hypothesis, the performance of the study (hypothesis testing), the collection of data from the study, data analysis, interpretation of the data, and the formulation of conclusions.

Study Design

Literature searches are essential to every step of an investigation, from beginning to end. They are critical to establishing a hypothesis and determining whether there are sufficient preliminary data to justify a study, define the study parameters, establish safety and inclusion criteria, and assess study endpoints.

Literature searches can be performed free of charge on web-based databases such as PubMed or via a library with databases such as Ovid. Furthermore, software solutions such as EndNote and Reference Manager will help speed up a literature search and facilitate the categorization and storage of publications in your database query. Direct communication with other research and medical experts is also helpful for hypothesis generation. The checklist below can be beneficial for study design planning.

1. Identify and document a problem, uncover an idea, and perform a literature search.
2. Develop a clear definition of the problem.
3. Identify possible solutions and formulate a null and an alternate hypothesis.
4. Define the study population and the sample size required to disprove the null hypothesis.
5. Create a database to store data.
6. Create a subject recruitment plan or a sample acquisition process.
7. Develop or select a statistical analysis plan, measurements, data collection tools, analytical tools, and biostatistics software.
8. Develop data collection forms or adapt software for data collection.
9. Define and assess confounders and bias.
10. Assess project feasibility and budget.
11. Consider human subjects, regulatory approval compliance, data use, and safety requirements.
12. Seek expert review and opinions.
13. Collect experimental data and demographic data.
14. Collect study outcome data.
15. Assess and analyze data and perform biostatistical analysis.
16. Interpret data/results.

本书版权归John Wiley & Sons Inc.所有

Hypothesis Generation

Formulation of a hypothesis is the most critical process in POR and is the core of a clinical research proposal (11). Hypotheses are generated from (i) data associations from epidemiological or observational studies, (ii) animal or *in vitro* data, (iii) direct observations in a patient or patient group, or (iv) already established but unproven interventions or strategies. Several essential questions must be asked in the formulation of a hypothesis (1).

- Is the research question relevant? Will answering it improve care?
- Has the question already been answered elsewhere? If so, was the study of sufficient power and breadth, or have conclusions been confirmed?
- Is the answer relevant to patient care, elucidating a biological mechanism, or establishing drug or device efficacy or safety?
- Can the hypothesis be proven, given the constraints involved in POR?
- Is it safe to perform the study?
- Are endpoints well established to determine efficacy?
- Can an adequate number of patients be enrolled to determine a definitive result?
- What is the next step in the design of the study to test the hypothesis?

Sampling the Population

Choosing the appropriate study population and sample size is integral to the study design. One approach is to recruit subjects or gather specimens from individuals with a well-established medical condition. Choosing a representative population with adequate representation of age groups, ethnicities, and genders will facilitate the generalization of the results to other groups.

Deciding on Sample Size, Measurements, and Endpoints

The design of a clinical research study helps determine the number of subjects or samples needed to power the study sufficiently. It may be necessary to consult with a biostatistician to properly assess power, study design, endpoints, and method of data analysis. The investigator's choice of study endpoints includes (i) clinical characteristics (also called variables) and (ii) a surrogate endpoint. A clinical endpoint is a characteristic that characterizes patient function or survival and may include physiologic markers and events (12, 13). A surrogate endpoint is expected to predict clinical benefit, or the lack thereof, based on epidemiologic, therapeutic, pathophysiologic, or other scientific evidence (14). A biomarker is "a characteristic objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention" (14).

Feasibility

The success of the study is dependent on several feasibility factors, which must be considered in the project design phase. The factors include the availability of research subjects, the ability to recruit research subjects into the study, the availability of the techniques and personnel required to measure study endpoints, expertise in using these techniques, and the adequacy of funds to cover research costs (1).

Confounding Variables and Bias

In statistics, a confounding variable (also called a confounding factor or confounder) is an extraneous variable in a statistical model that correlates (positively or negatively) with both the dependent and independent variables. The effect of a confounding variable is that a perceived relationship between an independent variable and a dependent variable can be incorrectly estimated due to the failure to account for the effect of a confounding factor. It is critical to control for confounding effects to isolate the impact of the variables of interest. For any research study, it is essential to determine whether it will answer the research question raised. In laboratory-based research, the control of confounders may be more easily achieved, as the investigator can match samples for many baseline characteristics and have control over the environment during the study.

Considering subject age, gender, race, and comorbidities can help the investigator match subjects in a control and an intervention group. In clinical research, controlling for confounders is often more challenging. When the effects of confounders are not well controlled, they are usually mitigated through statistical adjustment, i.e., the use of regression analyses (15–17); however, assessing the impact of confounders on study outcomes by these techniques may be inadequate (15–17).

Human Subject Protection

Clinical investigators must ensure the safety of each research subject. Exclusion criteria are established to prevent subjects with a higher risk from participating in the research study. All studies are reviewed by an institutional review board (IRB). Refer to chapter 41 in this volume for further discussion.

Collecting and Storing Data

Storing data in a properly designed data log and database is critical. Ideally, a spreadsheet or database is developed before the study begins. Data collection documents range from a simple Excel file to an Access database or any more extensive databases or electronic data capture software

本书版权归John Wiley & Sons Inc.所有

used for research purposes. Descriptive information may include demographic data, such as age, sex, ZIP code, and ethnicity. Intermediate data variables include laboratory test results, turnaround time, antimicrobial prescriptions, ventilation, etc. Clinical and operational outcome data examples include length of stay, mortality, readmission, etc.

The best experimental designs allow data to be electronically transferred from one database to another and standard statistical software without manual reentry. Manual data entry is prone to error but may be necessary. Some ways to decrease error risk in a spreadsheet include creating drop-down boxes, yes/no buttons, or "pick lists" to limit the typing required. Other practical processes include barcoding, double-checking data entry, training personnel who perform data entry, regularly reviewing the entered data for accuracy and consistency, and using appropriate programs to identify outliers due to manual data entry errors.

Because laboratory data typically include private or sensitive information, the database must be set up in a secure system that complies with IRB requirements, Health Insurance Portability and Accountability Act (HIPAA) regulations, and relevant data-use agreements. Most hospitals support compliant systems to keep data on secure servers unless appropriate accommodations are made to secure the data.

Data Analysis and Conclusion Formulation

The data analysis plan is one of the most critical elements of a clinical research study. It helps determine the number of subjects or samples needed to power the study sufficiently. Forming accurate conclusions that do not go beyond the data is a critical aspect of research. After critically reviewing the data analysis and assessing for bias, confounders, and other study limitations that may impact results, researchers formulate their conclusions and consider study limitations in the context of the data. After analysis, researchers must ask if the data are strong enough, when standing alone, to recommend a change in practice (definitive) or if further studies are required. Investigators must establish whether the null hypothesis was rejected, assessing the alpha error, sample size, and study power (18–20). Investigators must critically evaluate any unexpected results and study limitations. Finally, investigators must consider the need for future studies and develop an action plan. Biostatistical assessment and collaboration with a biostatistician help define the study's conclusions.

Traditional Biostatistics

Descriptive Statistics

Critical analysis and assessment of biostatistics are essential for interpreting literature, conscious participation in clinical trials, translational research, basic research, publication of data, intelligent conversation with statisticians, and documentation of evidence-based improvements due to laboratory interventions (21). Certain test attributes are used as descriptive statistics for method verification or validation that should be reported with confidence intervals; however, comparative (inferential) statistics can also be used and are often warranted (21). Attributes such as accuracy, precision, analytical sensitivity, analytical specificity, analytical measurement range (limit of quantitation and linearity), reportable range, normal values, and other attributes may apply.

Inferential Statistics: Issues for Medical Devices

Statistical issues in medical device studies include almost all those confronted by clinical trials of pharmaceuticals. Unique statistical challenges posed by medical devices (22) include considerations of sample size and power, handling of missing data, survival analysis, analysis of quality-of-life variables, interim analysis, and adjustments for the multiplicity of primary or secondary endpoints or hypotheses, sample size re-estimation, and meta-analysis. For *in vitro* devices, noninferiority statistics are standard, both for premarket announcements (PMAs) and for premarket notifications [510(k)s], where the focus is on "substantial equivalence" in diagnostic accuracy. For noninferiority studies, determining the noninferiority margin (i.e., the percent difference allowed between the methods) is a critical component.

In contrast, when a new device is compared to a reference standard, there is a possibility that the novel device is superior, in which case traditional comparative statistics may be used (23). However, several statistical issues are unique to medical device studies, specifically, blinding of the bench technologists and investigators, as well as biases introduced by the testing personnel and the type of specimens used. In many cases, the studies performed on *in vitro* devices may not be randomized because there is a single concurrent comparison group with a historical control or two simultaneous experimental arms but no randomization. In contrast to pharmaceuticals, where RCTs are the norm, few *in vitro* laboratory devices seeking regulatory approval in the United States have well-controlled, randomized clinical trials submitted to the FDA, and such studies are not required. Even for a class III device involving a PMA submission, historical controls are often used rather than a randomized clinical trial.

These circumstances pose a challenge to those who use statistical inference methods. Without subject or sample randomization, one needs to emphasize the bias description in the experimental design. Causal inferential methods, particularly propensity scores, help assess whether the historical control can provide a valid comparator. The propensity score methodology has been applied in

本书版权归John Wiley & Sons Inc.所有

medical device studies to provide insight into the relationship between the historical control data and those of the current new device (24). In some cases, the control group's performance is so well characterized that, rather than point to a particular data source for the historical control, an objective performance criterion (OPC) or a performance goal is established by experts using publicly accessible data. With this approach, if the new device performs according to the specifications found in the OPC, its safety and effectiveness can be demonstrated. Some statistical issues include the sample size necessary for such an assessment and how to incorporate variability into the OPC.

It is estimated that about 30 to 35% of medical devices are diagnostic, some are introduced into the clinical laboratory, and some are for pharmaceutical studies that rely on diagnostic or monitoring devices for the inclusion and exclusion criteria or to describe disease progression or recurrence. The simultaneous development of both a novel pharmaceutical agent and a new diagnostic test (also called companion diagnostics) can be challenging, as the companion diagnostic indicates who should or should not take the pharmaceutical agent.

There are imposing statistical issues about how to design such studies. The FDA released a draft white paper titled "Drug-Diagnostic Co-Development Concept Paper" on how to develop prospectively both a biopharmaceutical product and a diagnostic device in a scientifically, robust, and efficient manner (24). A fundamental issue concerns the claim for the diagnostic product in a drug-diagnostic codevelopment. Determination of a prognostic claim for the diagnostic product reporting the natural history of the disease (or condition) versus a predictive claim in that the result of the diagnostic test predicts the likelihood of a patient's response to the novel drug therapy is an important classification (16).

The statistical tools for designing and analyzing diagnostic test evaluations differ significantly from those used in therapeutic experiments and pharmaceutical studies, which use well-defined statistical methods. The statistical problems in diagnostics are, in some ways, more challenging. In many situations, randomization is abandoned in favor of a much more efficient and less costly design that compares two diagnostic tests by applying both tests to the same individuals or samples. If the order of testing matters, then the study design can specify a randomization approach for the order of test performance. Still, the randomized parallel design is somewhat rare except for the evaluation of screening tests. Since an RCT is generally cost prohibitive for diagnostic methods, the paired study design is usually preferred for power considerations and the sample size. For diagnostic test evaluation, the different types of bias become enormously concerning to statisticians (25, 26).

Challenges for Diagnostic Studies

For diagnostic studies, it is essential to distinguish whether the true disease state can be determined—is there a true gold standard? In cases where the truth is known and the test is dichotomous (e.g., positive or negative), the analysis reduces to truth tables (two-by-two tables) and the inference concerns confidence intervals or hypothesis tests for sensitivity, specificity, and positive and negative predictive values.

For diagnostics, one also often needs to establish the limit of detection, for which a nonparametric statistical approach can be used (27). For more detail on reporting the results of such diagnostic tests, refer to the document "STARD 2015: an Updated List of Essential Items for Reporting Diagnostic Accuracy Studies" (21).

In many situations, either there is no gold standard or its use is impractical in evaluating a diagnostic product. In these instances, the ideal situation would be to calibrate the new test to the known performance of the reference standard. If such a calibration cannot be carried out, the indiscriminate use of terms such as sensitivity and specificity is discouraged due to the bias that an imperfect reference standard might introduce.

In agreement studies, the focus is on evaluating a diagnostic test by assessing its agreement in performance with some other well-understood but imperfect test. In such cases, positive and negative agreement are the preferred terms. When the true disease state is unknown, a latent variable analysis may be used to estimate the performance of the new tests being studied and the unknown disease prevalence.

Recently, FDA-approved tests describing the host immune responses have used clinical endpoint adjudication (CEA) as the gold standard. CEA is a standardized process for assessing the safety and efficacy of pharmacologic or device therapies in clinical trials. CEA can play a role in large clinical trials to achieve consistency and accuracy of the study results by applying independent and blind evaluation of suspected clinical events reported by investigators. Further research and evidence in this field of clinical trial methodology are essential.

In diagnostic test evaluation, there are also situations in which the truth may be known, but only for a subset of subjects or samples. In such cases, adjustment for verification bias is imperative because establishing the validity of the patient's condition depends inherently on the test or tests applied to the patient. An example of this would be "discrepant testing," a resolution of discrepancy in which discordant results between the two methods receive further testing. Although commonly reported, this practice introduces a bias toward confirmation of the new test and is discouraged. Various biostatistical methods can be applied to evaluate clinical laboratory methods. For example, with continuous or ordinal data, the

本书版权归John Wiley & Sons Inc.所有

usefulness of the receiver operating characteristic methodology is relevant for evaluating diagnostic tests when there is a highly reliable reference standard (28, 29). In contrast, method comparison techniques assess the accuracy of two diagnostic tests in the absence of truth. Techniques like Deming or orthogonal regression are used (30, 31). Unique challenges exist for assessing microarray data and statistical and regulatory issues associated with microarrays and other genetic tests (22, 32). Finally, for inferential questions that evaluate the equivalence of two diagnostic tests, one must determine comparability (i.e., whether the slope is 1 and the intercept is 0). Note that the use of statistical methods to establish the (two-sided) equivalence of two different methods (33) is very similar to the question of equivalence in the study of generic drugs (34).

Other Research Considerations

Continuing medical education and habits of lifelong learning are key to the future of clinical laboratory science. For laboratory scientists who are working in quality control, quality assurance, or evidence-based medicine or who are considering a research career or graduate school, coursework with a focus on biostatistics, regulatory issues, grant writing, experimental design, and clinical trial development is beneficial. In addition, as clinical research expands, clinical laboratories are often asked to provide core services for deidentified specimens. Personnel should be trained to comply with good banking practices or best practices for biorepositories if they perform this role. More advanced coursework may also be available through certificate programs or master's-level programs in clinical sciences, public health, biostatistics, epidemiology, applied biosciences, and other programs. Such training supports career advancement in research track positions, such as study coordinators, quality assurance staff, laboratory management, and directorship.

Systematic Reviews and Laboratory Medicine Best Practices

Evidence-Based Laboratory Medicine

The principles of evidence-based medicine (EBM) were established because of the need for evidence-based clinical practice. EBM is accepted in most health systems and can be deployed in laboratory medicine (EBLM). The definition of "EBLM" in reference 35 is "the conscientious, judicious, and explicit use of best evidence in the use of laboratory medicine investigations for assisting in making decisions about the care of individual patients." The key steps in evidence-based practice are (i) formulating the question, (ii) searching for evidence, (iii) appraising evidence, (iv) applying evidence, and (v) assessing the experience. Despite the consensus, translating EBLM into daily practice has been slow. Contrasting observations and challenges include the expected definitions of a sufficient sample size to document impact, the expense and time spent gathering evidence, and differences in the perception of actionable testing in different healthcare organizations. Integrating the principles of EBLM into routine practice will help to resolve some of these issues by better identifying where laboratory medicine fits into the care pathway, where testing is appropriate, the nature and quality of evidence required to demonstrate the clinical utility of a test, how the test result impacts clinical actions, where changes in the care pathway will occur, and where the benefit or value can be achieved.

Historically, laboratories have stored and analyzed large amounts of data; however, there are many instances in which the utility of the data is not well explored. Compilation and analysis of laboratory data linked to clinical information are critical to documenting impact. The emerging field that the lead author named "interventional diagnostics" embraces the examination and analysis of the impact of diagnostic test intervention on patient care. Data to describe the postanalytical effects of actionable interventions based on relevant laboratory tests are the key to the future of laboratory science and the growing awareness of the importance of laboratory medicine to nearly all aspects of healthcare practice.

Clinical laboratory scientists have been leaders in quality assurance practice for decades but have not always shared results in peer-reviewed literature to improve patient outcomes further. The laboratory intervention approach to research aligns with EBM. This practice uses existing data to answer questions and solve problems through systematic synthesis and appraisal of data. In the EBM process, standardized data acquisition and analysis are used so that the data derived from the process will add to the evidence-based body of knowledge. The underlying premise of an evidence-based approach is that healthcare decisions are guided by synthesizing and appraising evidence from well-designed studies balanced with clinical expertise and individual patient preferences.

The Agency for Healthcare Research and Quality (AHRQ) is one leader in this initiative, dubbed "Patient-Centered Outcomes Research" (36). The Centers for Disease Control and Prevention's Laboratory Medicine Best Practices (LMBP) initiatives (37) adapt EBM concepts to clinical laboratory practice and quality improvement (QI) studies. Current LMBP systematic reviews are available and are described in general terms (38). Challenges to practicing EBM in laboratories include the lack of research time allocated to the clinical laboratory; the lack of experimental design and biostatistical training in medical laboratory science (MLS) programs and fellowships; the lack of

本书版权归John Wiley & Sons Inc.所有

institutional support for mentoring and implementing an evidence-based approach; the lack of evidence from well-designed diagnostic studies; and misconceptions about practicing and contributing to EBM (38–40).

Laboratory Medicine Best Practices Initiative

The premise of evidence-based practice recommendations relies on two processes, systematic reviews and meta-analysis (see Fig. 42.1) (38). A systematic review collates and analyzes the findings from well-designed studies and pools the results from individual studies to reduce bias and maximize the interpretation of the conclusions. Various terms are used for systematic reviews, including "comparative effectiveness" and "patient-centered-outcome research." Still, the common objective is to use available data to make optimal decisions for diagnostic laboratory practice and patient care. Systematic review methods consist of crucial steps to address a problem about the quality of certain laboratory practices (38, 39).

Considering that evidence generated in the laboratory is typically derived from observational studies rather than randomized controlled trials, the LMBP A-6 methods are applied to conduct reviews that assess the effectiveness of practices in improving the quality of laboratory medicine service delivery. Within LMBP, systematic reviews can provide information to support decision making for health outcomes achieved from using a diagnostic test and other outcomes that influence the cost and quality of patient care (e.g., decreased mortality, inpatient length of stay, and earlier treatment). Via the LMBP systematic review process, unpublished QI data, typically not disseminated through the peer-reviewed literature process, are incorporated with data from the peer-reviewed literature. QI data may be hampered by a lack of the following elements of sound research design—the explicit focused purpose of the study, defined sample size, the defined practice of interest, collection of baseline data or data on the usual (or current) practice (comparator), and defined outcome measures (38, 39).

Fundamental evidence-based practice principles to improve QI projects include:

1. Framing quality problems as clinical questions using what is called the PICO (population, intervention, control, and outcomes) format
2. Conducting literature searches
3. Applying elements of research study design to the QI project design
4. Capturing and disseminating project results

A systematic review is designed to answer a clearly stated question. The essential steps in a systematic review process include:

1. Posing an explicit statement of one or more clinical questions
2. Developing a search strategy for published primary studies
3. Reviewing titles and abstracts generated by the search
4. Selecting and reviewing full papers and extracting relevant data
5. Analyzing data, including the use of meta-analytic tools
6. Summarizing findings
7. Identifying further research needed

Types of PICO questions and measures (40–42) include:

Intervention: What practice, policy, or therapy leads to the best outcome?

Diagnostic: Which test is more accurate and precise in diagnosing a condition?

Prognosis: The likelihood of a particular outcome for a population with specific changes observed in the results of laboratory questions.

For example, for a rapid PCR (rPCR) method comparison (38), PICO would include the following:

1. *Population (sample):* All adult inpatients with a positive blood culture result for *Staphylococcus aureus* bacteremia admitted during the study period; pre-rPCR = 74 patients, post-rPCR = 82 patients.
2. *Intervention (practice evaluated):* Rapid technology (rPCR) with communication; rPCR result paged to infectious diseases (ID) pharmacist Monday to Friday 8 a.m. to 5 p.m. or logged by laboratory and reviewed by ID pharmacist next business day.
3. *Comparison practice:* Gram stain, final identification, and antibiotic susceptibility were completed in 24 to 72 hours and reported in electronic medical records without notification to a physician.
4. *Outcome:* In this scenario, a probable outcome could be a reduced time to targeted therapy.

However, it would be essential to list the definition of the outcome and how it was recorded. Staff at a hospital laboratory conduct a quality improvement project to assess whether employing rPCR with direct communication of results improves the time to report the identification of microbes causing suspected bloodstream infections. The project involves just one hospital and compares reporting times before and after the deployment of the rPCR with direct communication.

Outcome measurement source/recording could include reduction in time to targeted therapy and time from identification of positive blood culture to receipt of antimicrobial therapy by a patient for a specific type of bloodstream infection from chart review.

For the analysis in the American Society for Microbiology collaboration with the CDC LMBP Initiative,

本书版权归John Wiley & Sons Inc.所有

a review team of experts, such as those in clinical microbiology, biostatistics, epidemiology, laboratory sciences, infectious diseases, healthcare management, and other related specialties, is compiled. This team works to perform and document literature searches using PubMed (www.pubmed.gov; accessed 8 February 2023) and other resources such as the Cochrane Library (www.cochrane.org; accessed 8 February 2023), to search the current peer-reviewed literature to identify publications, called primary studies. The team reviews primary studies, unpublished QI projects, and other literature using a critical appraisal checklist (Appendix 42.1) to evaluate the quality of published primary studies. This LMBP study quality appraisal checklist can also guide further planning and documentation of QI projects, standards, or guidelines for optimal laboratory practice (33, 37, 38) and provide templates for preparing a publication about the findings of a project.

Using Machine Learning for Prediction

Artificial intelligence (AI) and the subset of AI known as machine learning (ML) are increasingly being utilized in medicine, to inform medical research, and in laboratory medicine, including infectious disease diagnostics (43–47). The approach is also under increasing scrutiny, and ethical challenges remain (48–50). While innovations have been booming in recent years, most ML in healthcare is focused on early disease detection, improved accuracy of disease diagnosis, risk stratification, pattern recognition in human physiology, and personalized diagnostics and therapeutics. While interest in ML applications within medicine is growing, few studies have progressed to deployment in patient care (51, 52).

Guidelines for accelerating the translation of machine learning-based interventions in healthcare will require a team of engaged stakeholders and a systematic process from beginning (problem formulation) to end (widespread deployment) (51). Integrating social determinants of health is imperative for ML to achieve full adoption in diverse healthcare settings (52). Furthermore, the challenge of changing data patterns that would require update of deployed ML models has yet to be fully defined (53–55) and education of the healthcare workforce to understand the advantages and limitations of AI and ML will be a large undertaking, even for a basic understanding (56–58).

The benefits and limitations of ML are well described in a review of models predicting COVID-19 outcomes, characterizing relative strengths and limitations of traditional biostatistics versus that of ML prediction (59). In 2018–2019, the FDA published reports describing the agency views on software precertification and proposed a working model (60). A pilot program was implemented to test the model and describes how the FDA intends to determine that the framework proposed provides reasonable assurance of safety and effectiveness for software as a medical device product. In 2021, a companion action plan was published (61), in response to stakeholder feedback to the FDA's 2019 Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software Medical Device.

Because AI and ML are techniques sometimes used to design and train software algorithms to learn from and act on data, the derived software, if intended to treat, diagnose, cure, or prevent disease or other conditions, is defined as a medical device under the Food, Drug and Cosmetics Act and is called "software as a medical device" (SaMD). The FDA has authority to regulate SaMD and has implemented a number of policies intended to guide the industry in safe practices for the development and use of SaMD (62).

SUMMARY

Clinical laboratory scientists are leaders in quality assurance practices and are poised to engage in research opportunities that further improve patient outcomes. In some cases, students and professionals will require new skills to leverage benefits to the healthcare system. Guidance can be found in the long-standing approaches to experimental design, data analysis, and biostatistics used in the pharmaceutical sciences. Government and professional societies are leading evidence-based initiatives for the diagnostics community. Active participation in such activity can broaden clinical laboratories' impact and contribute value to health improvements. ML and AI strategies are beginning to impact the practice of laboratory medicine, and federal and state regulations will continue to evolve with regard to their use in healthcare.

KEY POINTS

- Clinical research is a valuable component of healthcare improvement that benefits from participation by clinical laboratories.
- The clinical laboratory can adopt various study designs and data analysis methods.
- Translational research can be described as transitioning basic research practices and findings to daily use in a clinical setting, such as the clinical laboratory.
- Systematic reviews and meta-analyses are fast becoming valuable tools to improve or direct clinical laboratory guidelines.
- Evidence-based laboratory medicine can identify reasons for improvements and help standardize best practices for laboratory medicine.

本书版权归John Wiley & Sons Inc.所有

GLOSSARY

AHRQ Agency for Healthcare Research and Quality. The AHRQ is one leader in the initiative dubbed "Patient-Centered Outcomes Research."

AI and ML Artificial intelligence and machine learning. Artificial intelligence in medicine is the use of machine learning models to search medical data and uncover insights to help improve health outcomes and patient experiences. Currently, the most common roles for AI in medical settings are clinical decision support and imaging analysis. Clinical decision support tools help providers make decisions about treatments, medications, mental health, and other patient needs by providing quick access to information or research relevant to their patient. In medical imaging, AI tools are being used to analyze computed tomography scans, X rays, magnetic resonance images, and other images for lesions or other findings that might be missed by the radiologist.

Care pathway Plan for patient care that is comprehensive and integrated, meaning that it covers patient care from beginning to end. A good care pathway includes an explicit statement of the goals and key elements of care.

Descriptive statistics Certain test attributes are used as descriptive statistics for method verification or validation that should be reported with confidence intervals. Attributes such as accuracy, precision, analytical sensitivity, analytical specificity, analytical measurement range (limit of quantitation and linearity), reportable range, normal values, and other attributes may apply.

EBM Evidence-based medicine. EBM is accepted in most health systems and can be deployed in laboratory medicine (EBLM). The definition of EBLM is "the conscientious, judicious, and explicit use of best evidence in the use of laboratory medicine investigations for assisting in making decisions about the care of individual patients." The key steps in evidence-based practice are (i) formulating the question, (ii) searching for evidence, (iii) appraising evidence, (iv) applying evidence, and (v) assessing the experience.

Inferential statistics There are two main areas of inferential statistics. (i) Estimating parameters means taking a statistic from the sample data (for example, the sample mean) and using it to say something about a population parameter (i.e., the population mean). (ii) Hypothesis tests use sample data to answer research questions. For example, one might be interested in knowing if a new cancer drug is effective. Inferential statistics is used with sample data from a small number of people to try to determine if the data can predict whether the drug will work for everyone (i.e., the population).

Interventional diagnostics Interventional diagnostics embraces the examination and analysis of the impact of diagnostic test intervention on patient care. Data to describe the postanalytical effects of actionable interventions based on relevant laboratory tests are the key to the future of laboratory science and the growing awareness of the importance of laboratory medicine to nearly all aspects of healthcare practice.

LMBP Laboratory medicine best practices. Within LMBP, systematic reviews can provide information to support decision making for health outcomes achieved from using a diagnostic test and other outcomes that influence the cost and quality of patient care (e.g., decreased mortality, inpatient length of stay, and earlier treatment).

Meta-analysis Process by which the results of multiple individual studies are statistically combined.

POR Patient-oriented research. This includes (i) mechanistic (physiological) studies of human disease, involving the detailed investigation of a biological process; (ii) therapeutic studies, which focus on treatment designed to improve a disease or condition; and (iii) clinical trials, which are most often extensive, definitive studies from which data are submitted to the FDA for review when new drugs, technologies, and devices are planned.

REFERENCES

1. **Seely EW**, **Grinspoon S**. 2017. Patient-oriented research, p 9–23. *In* Robertson D, Williams GH (ed), *Clinical and Translational Science*, 2nd ed. Academic Press, New York, NY.

2. **Asher HB**. 1983. *Causal Modeling*. Sage, Beverly Hills, CA.

3. **Ewald H**, **Ioannidis JPA**, **Ladanie A**, **Mc Cord K**, **Bucher HC**, **Hemkens LG**. 2020. Nonrandomized studies using causal-modeling may give different answers than RCTs: a meta-epidemiological study. *J Clin Epidemiol* **118**:29–41.

4. **Chu H**, **Nie L**, **Cole SR**, **Poole C**. 2009. Meta-analysis of diagnostic accuracy studies accounting for disease prevalence: alternative parameterizations and model selection. *Stat Med* **28**:2384–2399.

5. **Leeflang M**, **Reitsma J**, **Scholten R**, **Rutjes A**, **Di Nisio M**, **Deeks J**, **Bossuyt P**. 2007. Impact of adjustment for quality on results of metaanalyses of diagnostic accuracy. *Clin Chem* **53**:164–172.

6. **Anello C**, **Fleiss JL**. 1995. Exploratory or analytic meta-analysis: should we distinguish between them? *J Clin Epidemiol* **48**:109–118.

7. **Savović J**, **Jones H**, **Altman D**, **Harris R**, **Jűni P**, **Pildal J**, **Als-Nielsen B**, **Balk E**, **Gluud C**, **Gluud L**, **Ioannidis J**, **Schulz K**, **Beynon R**, **Welton N**, **Wood L**, **Moher D**, **Deeks J**, **Sterne J**. 2012. Influence of reported study design characteristics on intervention effect estimates from randomised controlled trials: combined analysis of meta-epidemiological studies. *Health Technol Assess* **16**:1–82.

8. **Dou YH**, **Du JK**, **Liu HL**, **Shong XD**. 2013. The role of procalcitonin in the identification of invasive fungal infection-a systemic review and meta-analysis. *Diagn Microbiol Infect Dis* **76**:464–469.

9. **Jagminas L.** 2013. ACP Journal Club. Meta-analysis: procalcitonin-guided antibiotic therapy reduces treatment failure in acute respiratory infection. *Ann Intern Med* **158**:JC5.

10. **Haeusler GM**, **Carlesse F**, **Phillips RS**. 2013. An updated systematic review and meta-analysis of the predictive value of serum biomarkers in the assessment of fever during neutropenia in children with cancer. *Pediatr Infect Dis J* **32**:e390–e396.

11. **Inouye SK**, **Fiellin DA**. 2005. An evidence-based guide to writing grant proposals for clinical research. *Ann Intern Med* **142**:274–282.

12. **Levinson SS**. 2009. Clinical validation of biomarkers for predicting risk. *Adv Clin Chem* **48**:1–25.

13. **Biomarkers Definitions Working Group**. 2001. Biomarkers and surrogate endpoints: preferred definitions and conceptual framework. *Clin Pharmacol Ther* **69**:89–95.

14. **US Food & Drug Administration.** 2021. About biomarkers and qualification. https://www.fda.gov/drugs/biomarker-qualification-program/about-biomarkers-and-qualification#what-is. Accessed 19 September 2023.

本书版权归John Wiley & Sons Inc.所有

15. Normand SL, Sykora K, Li P, Mamdani M, Rochon PA, Anderson GM. 2005. Readers guide to critical appraisal of cohort studies: 3. Analytical strategies to reduce confounding. *BMJ* **330**:1021–1023.

16. Mamdani M, Sykora K, Li P, Normand SL, Streiner DL, Austin PC, Rochon PA, Anderson GM. 2005. Reader's guide to critical appraisal of cohort studies: 2. Assessing potential for confounding. *BMJ* **330**:960–962.

17. Rochon PA, Gurwitz JH, Sykora K, Mamdani M, Streiner DL, Garfinkel S, Normand SL, Anderson GM. 2005. Reader's guide to critical appraisal of cohort studies: 1. Role and design. *BMJ* **330**:895–897.

18. Columb M, Atkinson M. 2015. Statistical analysis: sample size and power estimations. *BJA Educ* **16**:159–161.

19. Wolk DM. 2017. Statistics for method verification of qualitative assays in clinical microbiology. *Clin Microbiol Newsl* **39**:59–68.

20. Whitfield NN, Wolk DM. 2019. Statistics for method verification of quantitative assays in clinical microbiology. *Clin Microbiol Newsl* **41**:93–100.

21. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig L, Lijmer JG, Moher D, Rennie D, de Vet HC, Kressel HY, Rifai N, Golub RM, Altman DG, Hooft L, Korevaar DA, Cohen JF, Group S. 2015. STARD 2015: an updated list of essential items for reporting diagnostic accuracy studies. *Clin Chem* **61**:1446–1452.

22. Campbell G. 2004. Some statistical and regulatory issues in the evaluation of genetic and genomic tests. *J Biopharm Stat* **14**:539–552.

23. Yue LQ. 2007. Statistical and regulatory issues with the application of propensity score analysis to nonrandomized medical device clinical studies. *J Biopharm Stat* **17**:1–13.

24. Hinman LM, Huang SM, Hackett J, Koch WH, Love PY, Pennello G, Torres-Cabassa A, Webster C. 2006. The drug diagnostic co-development concept paper: commentary from the 3rd FDA-DIA-PWG-PhRMA-BIO Pharmacogenomics Workshop. *Pharmacogenomics J* **6**:375–380.

25. Begg CB. 1987. Biases in the assessment of diagnostic tests. *Stat Med* **6**:411–423.

26. Schmidt RL, Factor RE. 2013. Understanding sources of bias in diagnostic accuracy studies. *Arch Pathol Lab Med* **137**:558–565.

27. Linnet K, Kondratovich M. 2004. Partly nonparametric approach for determining the limit of detection. *Clin Chem* **50**:732–740.

28. Wagner RF, Beiden SV, Metz CE. 2001. Continuous versus categorical data for ROC analysis: some quantitative considerations. *Acad Radiol* **8**:328–334.

29. Delacour H, Servonnet A, Perrot A, Vigezzi JF, Ramirez JM. 2005. ROC (receiver operating characteristics) curve: principles and application in biology. *Ann Biol Clin (Paris)* **63**:145–154. (In French.)

30. Atiqi R, van **Iersel C, Cleophas TJ**. 2009. Accuracy assessments of quantitative diagnostic tests for clinical research. *Int J Clin Pharmacol Ther* **47**:153–158.

31. Rudi K, Zimonja M, Trosvik P, Naes T. 2007. Use of multivariate statistics for 16S rRNA gene analysis of microbial communities. *Int J Food Microbiol* **120**:95–99.

32. Shi L, Tong W, Goodsaid F, Frueh FW, Fang H, Han T, Fuscoe JC, Casciano DA. 2004. QA/QC: challenges and pitfalls facing the microarray community and regulatory agencies. *Expert Rev Mol Diagn* **4**:761–777.

33. Morgan CJ, Aban I. 2016. Methods for evaluating the agreement between diagnostic tests. *J Nucl Cardiol* **23**:511–513.

34. Com-Nougue C, Rodary C. 1987. Review of statistical procedures for determining the equivalency of two treatments. *Rev Epidemiol Sante Publique* **35**:416–430. (In French.)

35. Price CP. 2012. Evidence-based laboratory medicine: is it working in practice? *Clin Biochem Rev* **33**:13–19.

36. Department of Health and Human Services. April 2023. Agency for Healthcare Research and Quality. https://www.ahrq.gov/. Accessed 3 May 2023.

37. Centers for Disease Control and Prevention. 28 November 2018. Improving quality in laboratory medicine. https://www.cdc.gov/labbestpractices/index.html. Accessed 3 May 2023.

38. Shaw CS, Mass D. 2012. Evidence to practice: building the evidence for quality improvement in laboratory medicine. *Clin Leadersh Manag Rev* **26**:16–20.

39. Christenson RH, Snyder SR, Shaw CS, Derzon JH, Black RS, Mass D, Epner P, Favoretto AM, Liebow EB. 2011. Laboratory medicine best practices: systematic evidence review and evaluation methods for quality improvement. *Clin Chem* **57**:816–825.

40. Horvath AR, Pewsner D. 2004. Systematic reviews in laboratory medicine: principles, processes and practical considerations. *Clin Chim Acta* **342**:23–39.

41. Straus SE, Glasziou P, Richardson WS, Haynes RB. 2011. *Evidence-Based Medicine: How to Practice and Teach EBM*, vol 4. Churchill Livingstone Elsevier, New York, NY.

42. Price CP, Christenson RH. 2008. Evaluating new diagnostic technologies: perspectives in the UK and US. *Clin Chem* **54**:1421–1423.

43. Rashidi HH, Tran NK, Betts EV, Howell LP, Green R. 2019. Artificial intelligence and machine learning in pathology: the present landscape of supervised methods. *Acad Pathol* **6**:2374289519873088.

44. Peiffer-Smadja N, Rawson TM, Ahmad R, Buchard A, Georgiou P, Lescure FX, Birgand G, Holmes AH. 2020. Machine learning for clinical decision support in infectious diseases: a narrative review of current applications. *Clin Microbiol Infect* **26**:584–595.

45. Rashidi HH, Tran N, Albahra S, Dang LT. 2021. Machine learning in health care and laboratory medicine: general overview of supervised learning and auto-ML. *Int J Lab Hematol* **43**(Suppl 1):15–22.

46. Obstfeld AE. 2023. Hematology and machine learning. *J Appl Lab Med* **8**:129–144.

47. Peiffer-Smadja N, Dellière S, Rodriguez C, Birgand G, Lescure FX, Fourati S, Ruppé E. 2020. Machine learning in the clinical microbiology laboratory: has the time come for routine practice? *Clin Microbiol Infect* **26**:1300–1309.

48. Gruson D, Helleputte T, Rousseau P, Gruson D. 2019. Data science, artificial intelligence, and machine learning: opportunities for laboratory medicine and the value of positive regulation. *Clin Biochem* **69**:1–7.

本书版权归John Wiley & Sons Inc.所有

49. Doyen S, Dadario NB. 2022. 12 plagues of AI in healthcare: a practical guide to current issues with using machine learning in a medical context. *Front Digit Health* **4**:765406.

50. Chua M, Kim D, Choi J, Lee NG, Deshpande V, Schwab J, Lev MH, Gonzalez RG, Gee MS, Do S. 2022. Tackling prediction uncertainty in machine learning for healthcare. *Nat Biomed Eng* **7**:711–718.

51. Wiens J, Saria S, Sendak M, Ghassemi M, Liu VX, Doshi-Velez F, Jung K, Heller K, Kale D, Saeed M, Ossorio PN, Thadaney-Israni S, Goldenberg A. 2019. Do no harm: a roadmap for responsible machine learning for health care. *Nat Med* **25**:1337–1340.

52. Tricco AC, Hezam A, Parker A, Nincic V, Harris C, Fennelly O, Thomas SM, Ghassemi M, McGowan J, Paprica PA, Straus SE. 2023. Implemented machine learning tools to inform decision-making for patient care in hospital settings: a scoping review. *BMJ Open* **13**:e065845.

53. Zhang A, Xing L, Zou J, Wu JC. 2022. Shifting machine learning for healthcare from development to deployment and from models to data. *Nat Biomed Eng* **6**:1330–1345.

54. Weissler EH, Naumann T, Andersson T, Ranganath R, Elemento O, Luo Y, Freitag DF, Benoit J, Hughes MC, Khan F, Slater P, Shameer K, Roe M, Hutchison E, Kollins SH, Broedl U, Meng Z, Wong JL, Curtis L, Huang E, Ghassemi M. 2021. The role of machine learning in clinical research: transforming the future of evidence generation. *Trials* **22**:537.

55. Lee CS, Lee AY. 2020. Clinical applications of continual learning machine learning. *Lancet Digit Health* **2**:e279–e281.

56. Scott IA. 2021. Demystifying machine learning: a primer for physicians. *Intern Med J* **51**:1388–1400.

57. Linardatos P, Papastefanopoulos V, Kotsiantis S. 2020. Explainable AI: a review of machine learning interpretability methods. *Entropy (Basel)* **23**:23.

58. Lo Vercio L, Amador K, Bannister JJ, Crites S, Gutierrez A, MacDonald ME, Moore J, Mouches P, Rajashekar D, Schimert S, Subbanna N, Tuladhar A, Wang N, Wilms M, Winder A, Forkert ND. 2020. Supervised machine learning tools: a tutorial for clinicians. *J Neural Eng* **17**:062001.

59. Al-Hindawi A, Abdulaal A, Rawson TM, Alqahtani SA, Mughal N, Moore LSP. 2021. COVID-19 prognostic models: a pro-con debate for machine learning vs. traditional statistics. *Front Digit Health* **3**:637944.

60. US Food & Drug Administration. 2022. Digital Health Software Precertification (Pre-Cert) Pilot Program. https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-pilot-program. Accessed 19 September 2023.

61. FDA. 22 September 2021. Artificial intelligence and machine learning in software as a medical device. https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device. Accessed 3 May 2022.

62. FDA. 4 December 2018. Software as a medical device (SaMD). https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd. Accessed 3 May 2023.

APPENDIX 42.1 LMBP Study Quality Appraisal Checklist

STUDY SETTING

Is information about the study setting provided (e.g., intensive care unit, emergency department)?

Is the duration of the QI project or study (start and end dates) noted?

PRACTICE

Is there a practice description that includes requirements and components for operations?

Is the duration (start and end dates) for the practice reported?

SAMPLE SIZE

Is the sample population identified (e.g., samples, tests)?

Is the total number of observations for the sample size provided (e.g., the number of phlebotomy service blood collections)?

Are the selection criteria for participants or specimens provided (what was included and excluded)?

COMPARATOR PRACTICE (ORIGINAL OR USUAL PRACTICE)

Is there a comparator practice or standard (status quo)?

Are key characteristics of the original practice described?

OUTCOME MEASURES

Are the measurement(s) to assess practice impact identified and defined (e.g., length of stay)?

Are the measure(s) relevant to the QI question?

Is the method of data collection described?

RESULTS

Are the study results described and supporting data provided?

Are reported results related to the practice of interest?

APPENDIX 42.2 Resources for Professional Guidelines and Systematic Reviews

AHRQ National Guideline Clearinghouse
www.guideline.gov/index.aspx

AHRQ National Quality Measures Clearinghouse
http://qualitymeasures.ahrq.gov

AHRQ Innovations Exchange
www.innovations.ahrq.gov

Clinical and Laboratory Standards Institute
www.clsi.org/

Cochrane international network
www.cochrane.org

Laboratory Medicine Best Practices (LMBP)
https://www.cdc.gov/labbestpractices/index.html

本书版权归John Wiley & Sons Inc.所有

X

Defining and Measuring Standards for Success

(SECTION EDITOR: **Michael R. Lewis**)

43 Benchmarking and Performance Monitoring for the Clinical Laboratory
Lauren N. Pearson and Michael R. Lewis

44 Test Utilization and Clinical Relevance
Michael L. Wilson, Gary W. Procop, and L. Barth Reller

本书版权归John Wiley & Sons Inc.所有

本书版权归John Wiley & Sons Inc.所有

43

Introduction
Why Benchmark?
Types of Benchmarking
General Approach to Benchmarking and Performance Monitoring
Prioritization • Metrics Selection • Data Collection and Analysis • Development and Implementation of Plans
Interpretation of Benchmarking and Performance Monitoring Data
Interpretation of External Benchmarking Data • Interpretation of Internal Benchmarking Data • Data Interpretation in the Context of the Laboratory's QMS and Specific Quality Indicators That Are Evaluated
Challenges in Executing Benchmarking and Performance Monitoring
The Problems of Comparability and Selection Bias • The Problem of Cost Accounting • Selection of Indicators for Benchmarking and Performance Monitoring • Effects of the COVID-19 Pandemic Render Many Data from 2020–2021 Unhelpful for Comparisons
Measuring Laboratory Performance in the Broader Clinical Setting
Assessments for Patient Safety • Effect of Value-Based Payment Models (and Other Contemporary Influences) • Linkage of Payment to Measures of Quality • Laboratory-Related Standards in Broader Accreditation Programs
The Unattained Ideal: A Global Laboratory Benchmarking Scorecard Spanning Cost, Quality, and Operational Measures
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENTS
REFERENCES
APPENDIX

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch43.

Benchmarking and Performance Monitoring for the Clinical Laboratory

Lauren N. Pearson and Michael R. Lewis

OBJECTIVES

To discuss the reasons for undertaking benchmarking

To review the types of benchmarking activities and where to find benchmarks

To discuss the general approach to the most common types of benchmarking and performance monitoring—for productivity and cost

To discuss specific approaches to performance monitoring and external benchmarking

To discuss the interpretation of performance monitoring and external benchmarking data

To discuss the importance of selecting measures appropriate to the laboratory's strategy and environment

To discuss considerations relevant to the evaluation of benchmarking data

> *Measurement is the first step that leads to control and eventually to improvement. If you can't measure something, you can't understand it. If you can't understand it, you can't control it. If you can't control it, you can't improve it.*
>
> H. James Harrington

Measurement is a core activity in every clinical laboratory. We measure a wide variety of analytes for clinical purposes and report the results to support patient care. We do not report results without context, however—they are usually reported with reference ranges, so that physicians and other providers (and patients, too) can see immediately how a given result relates to what is expected in normal circumstances based on testing of otherwise healthy people. For some analytes (e.g., lipids), results are reported with broadly accepted guidelines for interpretation. The latter approach requires not only consensus on guidelines but also consistency of performance of the test; systematic error would lead to misclassification of results and harm to patients.

How do we measure analytical performance? For decades, clinical laboratories have engaged in proficiency testing and seen how their results stack up against those of other laboratories. For some analytes, there are standardization programs in which each laboratory's results are compared to those obtained by selected reference laboratories. Both types of comparisons take

本书版权归John Wiley & Sons Inc.所有

place multiple times a year to monitor analytical performance on an ongoing basis. As laboratory leaders, we can apply this approach of benchmarking and monitoring performance to the assessment of other aspects of our clinical laboratories' performance, such as quality in the preanalytical and postanalytical domains, stewardship of financial resources, human resources activities, and customer satisfaction.

In the most general sense, benchmarking is "the practice of measuring performance against a target using a specific indicator" (1). Valenstein and Schneider observe that "[w]hen we 'benchmark' a product or service, we compare its performance to an external standard. When we benchmark clinical laboratory quality, we compare local laboratory quality to an external quality standard drawn from studying many laboratories or a few best performers" (2).

Why Benchmark?

Motivations for benchmarking vary among laboratory leaders and organizations, but they may be distilled to a few primary purposes: pursuing quality improvement, fulfilling accreditation requirements, meeting payor requirements, positioning the laboratory in the marketplace, and enhancing strategic planning (2, 3).

Quality-focused benchmarking may reveal aspects of laboratory operations in need of improvement, helping leaders prioritize investments of focus and financial resources. Gaps between the laboratory's self-perceived level of quality and its current level of performance vis-à-vis benchmarks can bolster engagement of team members in quality improvement initiatives. The process of identifying suitable metrics for benchmarking may uncover emerging quality indicators that laboratory leadership will apply to enhance the quality management system (QMS) already in place.

Benchmarking is necessary if your laboratory is licensed or accredited by the Centers for Medicare and Medicaid Services (CMS), the College of American Pathologists (CAP), The Joint Commission (TJC), or other organizations concerned with ensuring the quality of clinical laboratory services. For licensure or accreditation, a laboratory must meet or exceed a series of externally imposed performance standards. CMS is charged by Congress, through the Clinical Laboratory Improvement Act (CLIA) of 1967 and its amendments in 1988 (CLIA '88), with regulating laboratory testing of specimens from human patients. While regulations may incorporate the basic or minimal standards for good practice, most voluntary accrediting agencies include far more stringent performance standards, reflecting principles that move an accredited laboratory's performance closer to that of the highest-performing laboratories.

Payor expectations and requirements drive benchmarking activities. Fulfillment of CLIA requirements and other applicable regulations is mandatory for participation in Medicare and Medicaid, which together make CMS the largest purchaser of laboratory services in the United States. Nongovernmental payors are increasingly establishing performance criteria that must be met if a laboratory is to have preferred "in-network" status or to provide covered services at all for covered patients. Ideally, such performance criteria are not set unilaterally by a payor but in collaboration with the laboratory, which can provide benchmarking data to inform the selection of indicators and targets.

Laboratories may approach payors, health system leaders, physician practices, and consumers with benchmarking data as a form of external validation of the quality of service that they may expect, as well as a reflection of the laboratory's commitment to providing high-quality service. These data may be useful in communications with current and prospective customers, and they may also help to frame discussions regarding what is realistic in terms of expectations on the part of payors, colleagues, and patients.

Picking benchmarks and attempting to understand what they mean in terms of your own performance may lead to an analysis of "what if" scenarios (or what could be called *strategic benchmarking*). During the planning for a benchmarking activity, you may realize that changes in the mix of customers, laboratory staff, or location of the laboratory would allow performance to reach even higher levels. Thus, benchmarking may eventually include an analysis of strategic changes (for example, the potential implementation of emerging technologies) as well as an analysis of process changes that may, in turn, alter the mission, vision, and goals of a laboratory. This process represents good business. Benchmarking is but one of many tools that a laboratory may employ to improve performance, focus on customers, and survive and thrive in an environment with limited resources.

For best efficiency, each process in the laboratory must perform close to the best balance between what is envisioned and what is possible. What is envisioned are the mission, vision, and goals of the laboratory personnel—why they are there, whom they want to serve, what they hope to accomplish, and how they plan to reach their goals. What is possible reflects the constraints imposed by the customers, equipment, facility, physical space, staff, funding, and organizational culture that the laboratory has acquired over time. Many of these constraints could be changed, but analyzing the effect of changing the constraints is much more than benchmarking. Benchmarking typically involves measuring a process and improving that process. Benchmarking is primarily focused on doing the best you can with whatever you have today, and it can help instill a culture of continuous process and performance improvement in the laboratory.

本书版权归John Wiley & Sons Inc.所有

One benefit of benchmarking is having contextualized performance data to inform discussions with institutional leaders regarding the laboratory's performance. If the laboratory and institutional managers can establish a mutually agreed-on definition of good performance, this may reduce reliance on formal external comparisons and place greater emphasis on performance monitoring, or the tracking of performance (using metrics) over time. Benchmarking and performance monitoring enable you to compete more effectively, obtain and retain resources for your laboratory, enhance the reputation of your department, and improve the satisfaction of your employees, providers, and patients.

Types of Benchmarking

Organizations both within and outside healthcare use benchmarking to evaluate performance in diverse areas such as financial performance, product quality and safety, employee development, customer satisfaction, human resources, marketing, and process improvement. While a laboratory manager's first instinct may be to locate benchmarks within the clinical laboratory industry, the search need not be firmly constrained within healthcare, as some business processes are common across many other industries. Thinking broadly about where you have received outstanding customer service or heard about excellent process improvement techniques reduces the likelihood of settling for suboptimal targets; it makes little sense to aim only for "best in class" status if the class as a whole needs improvement (4). Searching for information from other industries, whether related or not, may yield new insights into processes and introduce further improvements in performance.

Selection of variables for consideration and measurement requires a clear vision of the laboratory's strategy as well as precision with respect to defining measures that can guide subsequent decisions. Definitions must be clear, stable, and sensitive for detection of changes. That is, the measures must be sensitive and specific to the tasks that one seeks to measure. Identifying such measures is not straightforward. Information from colleagues at other institutions, as well as experience that has been published in the literature, can be of assistance in defining the types of measures that are sensitive and specific, though it is important always to remember that institutions differ in ways both obvious and subtle. Consequently, the degree to which experience at other institutions is analogous to that at your institution is always limited, just as performance of an assay, even using the same reagents, may yield different results in different settings.

Types of benchmarking may be categorized based on the organizational domain being benchmarked or by comparator. Domains may include quality (e.g., proficiency testing success rate, blood culture contamination rate, specimen identification error rate), financial performance (e.g., cost per billable test), operations (e.g., billable tests per testing full-time equivalent, instrument downtime rate), and human resources (e.g., employee turnover, engagement, burnout).

A comparator-based benchmarking classification may include internal benchmarking (as above, "comparison of a business process to a similar process inside the organization") and external benchmarking (3). *External* simply means outside the organizational unit engaged in the benchmarking activity; for example, external standards may originate in results of a nationwide survey or in the performance of other hospital-based laboratories in the same large health system. The latter is sometimes confusingly referred to as *internal benchmarking*: using a standard from other departments or divisions of the larger organization that are external to the unit using it as a benchmark but internal to the larger institution.

There are two types of formal external benchmarking approaches; in each, an external organization, which may be a for-profit entity or a not-for-profit group, provides a service. In one case, the benchmarking program for the laboratory is part of a comprehensive system that covers the whole institution, usually a hospital or a medical center. In the other case, the program is focused on laboratories and does not address issues outside of the laboratory. Two such programs have been described in published reports (5, 6).

Interfaces between people and between divisions or departments pose special challenges to laboratories, both operationally and with respect to measurement. It is easier to look at ourselves and our unit's performance in isolation than to assess how well our patients are being served by the complex systems in which we operate. Nonetheless, a superb laboratory within a dysfunctional institution has limited value. While it may be difficult to measure performance across interfaces, given the disparate data sources and frames of reference involved, effort invested here may be well rewarded by increases not only in performance level but also in the satisfaction of all involved. Employing several measures that address specific components of a process that involves interfaces may identify processes requiring attention. Once each component of the larger system is functioning at a reasonable level, however, a summary measure may not only prove more efficient for measurement and review but may also align the interests of those contributing to the process.

Many laboratories prefer and are most comfortable with benchmarks that are specifically tailored to the services that a laboratory provides. The College of American Pathologists (CAP) Q-Probes and Q-Tracks programs are excellent examples of quality-focused benchmarking (7). They allow laboratories to share competitive and best

本书版权归John Wiley & Sons Inc.所有

practices data in blinded studies focusing on areas that typically could be improved in most laboratories. Both programs extend beyond the laboratory environment to focus on key processes and areas of concern, including such issues as reducing telephone calls to a surgical pathology department through the incorporation of standardized reporting formats, measures of satisfaction with laboratory services, and effectiveness of services. Many of these studies are published in the *Archives of Pathology and Laboratory Medicine* and are also available on the CAP website (www.cap.org, accessed 16 February 2023); recent examples include a Q-Probes study assessing the impact of transit time on the detection of bacterial pathogens in blood cultures (8). Benchmarking using quality indicators has been pursued on an international scale by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Laboratory Errors and Patient Safety Working Group's Model of Quality Indicators (MQI) project (9).

Benchmarking, and in particular external benchmarking, brings added value and should complement performance monitoring in the laboratory's quality management system. A dual approach may be optimal: tracking performance internally to observe temporal changes, but also measuring local performance against the best in the field. To use a sports analogy, performance monitoring is like a sprinter measuring their performance only by comparison to their own previous efforts, without testing that performance against the best in the field; competing in a race would correspond to external benchmarking. It is possible to continuously improve without ever actually being very good.

General Approach to Benchmarking and Performance Monitoring

Prioritization

While details of the benchmarking process vary across organizations, some common themes emerge as one examines different approaches (Table 43.1) (10, 11). Begin your benchmarking process by prioritizing areas in which your organization should seek to improve, bearing in mind that the feasibility of benchmarking some processes may be limited. Dedicate time to determining the scope of the benchmarking project and to developing a realistic plan; make sure that the purpose of the project is clear to everyone on the benchmarking team. Enlisting the support of laboratory (and often institutional) leadership and the process owner(s) is a key step to ensure adequacy of time and resources to improve the process and prevent misalignment of stakeholders. We recommend defining a goal for future state if possible. The goal may be defined by the laboratory or directed by institutional stakeholders.

Table 43.1 Basic steps in the benchmarking process[a]

Prioritize areas in need of improvement.
Determine scope of the benchmarking project and develop a plan.
Enlist support of leadership and process owner(s) to ensure adequacy of resources.
Identify organizations against which to benchmark.
Define goal(s) for future state.
Collect data from comparison organizations.
Compare your organization's data against those obtained from the other organizations.
Develop plans for improving processes to close gaps between current and desired states.
Communicate with stakeholders and implement plans.
Monitor performance over time and recalibrate or replace benchmarks as needed.

[a] Adapted from reference 10.

Metrics Selection

Choosing metrics for benchmarking and performance monitoring requires balancing the ideal and the possible. There are a variety of sources that may be consulted for metrics that may be useful and that have been employed by other organizations. An excellent starting point for laboratories is to use metrics that are specifically pertinent to their work, such as quality metrics used in the previously referenced CAP Q-Probes and Q-Tracks programs. Examples of financial and productivity measures applicable in the laboratory setting may be found in Appendix 43.1. Resources, both in terms of information systems' reporting capabilities and the availability of knowledgeable team members to leverage those reporting tools, are limited, so measures that are built into the laboratory's systems may serve as a natural starting point from which to screen a proposed list of metrics or even from which to develop such a list.

Ideally, the metrics selected will not only be amenable to measurement with the available tools but reflect important aspects of performance. In some instances, the widespread adoption of electronic health records has expanded the ability to measure laboratory performance in a clinically relevant manner. For example, turnaround time may be assessed not only on an intralaboratory basis (e.g., from specimen accession time to result release time) but also from the time an order was placed until the result is first reviewed. (The discerning user of electronic health records will be quick to note that this does not include the time from a physician or provider's decision to order a test to when they have been able to successfully place the order; this may subjectively feel like one of the longer parts of the testing process.)

Sometimes decision making regarding metrics will occur outside the laboratory; if the hospital or health system, for example, contracts with a vendor to implement an

本书版权归John Wiley & Sons Inc.所有

institution-wide benchmarking program (often focused on financial and productivity measures), the laboratory may simply be handed a list of measures preselected for data collection. In such instances, it is imperative that laboratory leaders review the measures' definitions to anticipate any variations in their laboratory's data collection methods or organizational structure that may adversely affect comparability of their data with those from other organizations (see "The Problems of Comparability and Selection Bias" below).

Data Collection and Analysis

Every laboratory can generate spreadsheets filled with vast quantities of measurement data; the question becomes what to do with this information and how to use it to improve performance. It is easy to float adrift in megabytes of data and lose sight of the desired destination; the goal should not become the mere manipulation of the data collected.

Once you have selected metrics and identified internal departments or external organizations against which you would like to benchmark your organization's performance, collect the pertinent data, and compare your laboratory's numbers to the comparison group. Ensure that data collection and other standards are maintained throughout the measurement period and that there are sufficient resources so that parts of the planned analysis and measurement do not get delayed due to unavailability of key personnel. Be prepared to expand your analysis and plans for change beyond the scope of the original activity as new or additional relevant findings or needs are uncovered. Sometimes additional findings will include issues that impinge on a process and may be more relevant to the final analysis than originally anticipated. Organizational knowledge may facilitate better understanding of the effects of uncommon events on benchmarking data and on the underlying processes being assessed. Changing the way you manage these less frequent, but often very disruptive, variations in a process may result in a substantial but unexpected improvement in performance. Be prepared to communicate findings on an ongoing basis, so as not to surprise the process owner(s).

Development and Implementation of Plans

Finally, document your findings and develop plans for process improvement that will close the gaps between your organization's present state and the desired state as determined by your study. We recommend defining targets or stretch goals for any planned interventions. Take care to communicate effectively with team members and other stakeholders and ensure adequate piloting of planned changes. Consider a risk assessment of planned interventions. Make sure that there is adequate training of process owner(s) and staff in the new planned process. Implement your plan, monitor performance over time, document your findings, and plan for additional change(s). Throughout the process, apply good management techniques just as you would for any organizational change: pick your team members well, ensure buy-in of relevant groups, and keep up the team spirit throughout the project.

To realize the potential benefits of employing benchmarking data to assess laboratory performance, the leadership of the laboratory and/or the institution must not depend solely on numbers but use all available information to sort out where the problems are and where attention must be directed. We suspect that in many laboratories everyone knows where the problems, challenges, and opportunities are, although they may not be identified openly and honestly. Leaders must treat all members of the laboratory as if they are truly members of a team. Conversely, all members of the laboratory must truly believe that they are part of a team, that their efforts are recognized and appreciated, and that they will not be penalized for making sacrifices for the greater good. Such an approach requires an honest understanding of barriers and challenges, combined with a willingness to face them together. Whether the team is the laboratory as a whole or a subunit, attention is directed to improving key indicators over time.

Interpretation of Benchmarking and Performance Monitoring Data

Interpretation of External Benchmarking Data

When an external benchmarking approach has been chosen, the analysis can be more sophisticated and potentially more instructive, but the process is also more complicated. If external benchmarking is performed using a contracted service, the analysis is both assisted by and limited by the way the data are massaged and presented by the benchmarking service. It is obvious that limitations include the choice of items that are presented by the program and the statistical rigor of the presentation. The simplest presentation is a depiction of institutional data on a continuous scale with other participants, usually divided into quartiles or deciles. Viewing each item in isolation is a downside to this approach. A drawback of percentile analysis is that 25% of the participants will necessarily fall in the bottom quartile, even if everyone is performing adequately on an absolute scale. Conversely, 25% of participants will be able to celebrate a ranking in the top quartile, even if the performance of the group may be lackluster in absolute terms.

More sophisticated analytical schemes may present multiple relevant indicators in a single graphical summary; for example, one might include a productivity ratio on one axis and a cost ratio on the other axis. The best performers will have high productivity and low cost; the worst performers will conversely have high cost and low productivity.

本书版权归John Wiley & Sons Inc.所有

When external benchmarking is not performed by a contracted service, but rather by the laboratory against external entities or published data, attention to how data were collected and analyzed by both the comparison group and comparator is essential. This will help determine the validity of the comparison(s) and reveal any confounding variables that warrant caution for data interpretation. It is optimal if the data are analyzed and presented the same way by the laboratory and by the source of the external benchmarking data.

Interpretation of Internal Benchmarking Data

Internal benchmarking of laboratory performance against standards from other departments or units in the hospital has been less commonly employed than external benchmarking. With the ongoing expansion of health systems, however, there are increasing opportunities for meaningful comparisons of performance among laboratory units (e.g., hospital laboratories) within a given system. Some of the cautions typically weighed when engaging in external benchmarking likewise pertain in this setting. For example, comparability of the hospital laboratories must be weighed when considering their relative performance; if the system includes critical access hospitals with two dozen beds or fewer, large community hospitals with several hundred beds, and possibly academic medical centers as well, there will necessarily be differences in the scope of testing and in the patient and testing mix regardless of the level of commitment to standardization of procedures across the system's constituent units. Differences aside, interpretation of internal benchmarking data is an opportunity to determine where and why differences in quality or performance exist among laboratory units within a system. Investigation of root causes may reveal opportunities for standardization of processes and resources that can improve the overall quality of laboratory services in the system.

Data Interpretation in the Context of the Laboratory's QMS and Specific Quality Indicators That Are Evaluated

Once data are available for each indicator being benchmarked, it is tempting to jump quickly to explanations for the observations. Leveraging the laboratory's quality management system tools to investigate differences between measured performance and the benchmark standard or between current state and target performance is recommended. No analytical program can substitute for astute management, careful study of daily events in the laboratory, and most importantly, listening to peers and subordinates, but anecdotes and observations should be complemented by objective assessment of people and processes. This will help determine if the observed differences are clinically or operationally meaningful as well as inform the design for an intervention to improve performance. A comprehensive list and discussion of quality improvement tools is beyond the scope of this text. We refer readers to more definitive resources on the subject, but commonly utilized strategies for consideration include Lean Six Sigma and Failure Mode and Effects Analysis, among others (12, 13).

Given the complexity of laboratory function and the variability of available benchmarking programs, it is not possible to provide an exhaustive catalogue of all possible analytical permutations. In Appendix 43.1, financial and operational benchmarking data from four laboratories during one time period are compared and analyzed. Two of the laboratories (A and B) are similar, and these comparisons are closest to the ideal of "apples to apples." The other two laboratories differ in enough ways from each other and from the first two laboratories to make comparisons more problematic. In each instance, the benchmarking data should be viewed only as a starting point from which to work. The most useful purpose served by the comparisons is that they may point the way to valuable lessons about your own business and the road to improvement.

Challenges in Executing Benchmarking and Performance Monitoring

The Problems of Comparability and Selection Bias

One important issue that comes up is the lack of comparability of a given organization's structures or systems with those of other organizations. For example, one organization may not allocate a line item for overhead (e.g., for the executive office staff); instead, it loads all such costs, including utilities, into a charge per square foot for laboratory space. This approach makes line-by-line budget comparisons with other organizations that analyze costs in a more traditional manner very difficult, because the charge per square foot cannot be broken out into the components for utilities, overhead, etc. In another organization, costs for overhead are taken out and paid before a budget is allocated for the laboratory service. As a result, the laboratory managers in this organization do not have access to the fully loaded cost of their laboratory services.

Laboratories may also vary with respect to allocation of types of testing across sections or divisions; some uncommon arrangements may persist for years after evolving in response to particular laboratorians' interests and/or expertise. For example, consider the impact on a productivity metric such as billable tests per productive hour worked, if your laboratory includes esoteric testing in its hematology cost center, when the laboratories against which you are being compared do not. Thus, when seeking comparisons, it is essential to identify organizations that function and are organized in an equivalent manner so that the likelihood of making valid comparisons and consequently drawing valid conclusions is maximized.

本书版权归John Wiley & Sons Inc.所有

Imperfect comparability of preanalytic, analytic, and postanalytic processes between laboratories may limit the validity and usefulness of benchmarking activities in the area of quality performance. However, there can still be meaningful discovery of new or different ways of operating the laboratory that can be beneficial. Areas of opportunity for quality improvement may be identified even if the model for benchmarking is imperfect.

Selection bias may adversely affect the applicability of results from voluntary external benchmarking programs, as laboratories with quality concerns or more limited resources may not be as well represented among comparison groups as their better-resourced counterparts.

The Problem of Cost Accounting

Much attention has been paid over the years to financial benchmarking, yielding reams of data. Precision may appear great—down to the nearest cent. Unfortunately, the accuracy of allocation of cost to various clinical functions is problematic at best and sometimes misleading; benchmarks addressing personnel costs in the laboratory must be thoroughly understood. How comparable are the laboratories being compared in terms of services, size, and structure? What are the units of the benchmark? Lab payroll? Lab tests? Do the benchmarks make sense given the local laboratory's structure and services? Of note are costs allocated to the hospital laboratory that facilitate better quality and lower costs for the broader institution. Expensive virology services are but one example in which excessive focus on the direct testing expense, without concomitant attention to decreased length of stay or decreased risk of healthcare-related infection, may lead to decisions contrary to the hospital's broader goals. More and more hospital administrations are spending resources to generate broad benchmarks applicable to the laboratory and their functions throughout their institutions, but it is essential to set aside resources internally to develop and monitor appropriate performance measures in the laboratory.

Most laboratory professionals will agree that determining the cost of an individual laboratory test is very difficult. For tests performed in one of the relatively automated sections of the laboratory, such as chemistry or hematology, the true cost of a test will vary substantially with the shift, the day of the week, and the instrument on which it is performed. Most laboratories have multiple instruments or systems that may be used for performing some tests; for example, a test for blood glucose may be performed using point-of-care instrumentation or on a chemistry analyzer in the core laboratory. If the laboratory is responsible for the cost of both systems, what is the true cost of a glucose test? If an attempt is made to analyze performance at the level of methodology as well as analyte, the system becomes very complex. As discussed in chapter 30 of this volume, for batched tests, the cost of a test will vary with the size of the batch because the expense exhibits a stepwise, not linear, progression with increasing volume.

Even for less automated sections of the laboratory, such as microbiology and the blood bank, the problem remains difficult. Not all microbiology specimens are created equal; a specimen that yields no bacterial growth will generate costs in labor and materials that are very different from a specimen with several potential pathogens. Similarly, blood samples received for a pretransfusion antibody screen vary widely in the quantity of resources they require for complete testing. Once again, cost accounting becomes very complex if an attempt is made to account for each of the variables.

What, then, are some of the alternatives to detailed and specific financial benchmarks? One alternative is to move to a higher level, so that many of the distortions that occur in pricing individual tests average out across a section, division, or laboratory. One technique that many managers have used successfully in the past involves determining the total number of laboratory tests done (with or without tests referred to a reference laboratory) and the total budget of the relevant laboratory unit, then using these numbers to calculate an average cost per test. This approach might be termed "benchmarking by unit of service." Cost and productivity measurements at the level of the laboratory will be more accurate and reproducible than divisional data, which will, in turn, be more robust than test-specific data. As in epidemiology and financial analysis, ratios are much more useful than raw numbers. Examples of variables that are frequently analyzed and commonly used ratios are summarized in Table 43.2.

The simplest and most straightforward approach to evaluating financial performance is to use your own laboratory as the standard and monitor performance over time. What you gain by this maneuver is reproducibility, because management has control over the assumptions and can ensure consistency over time. In addition, departments, divisions, and laboratories within the organization that are difficult or impossible to compare against each other can legitimately be compared against themselves. It is not valid to expect the same productivity or expense in a cytogenetics laboratory as is required in an automated chemistry laboratory, but it is valid to ask each of those laboratories to make ongoing improvements in both productivity and cost on a continuing basis. By limiting the analysis to a single unit (the laboratory) within a single institution, however, management loses the value of comparing performance with peers in the industry, some of whom might even be competitors.

Selection of Indicators for Benchmarking and Performance Monitoring

As mentioned above, ratios are much more useful as indicators or metrics than raw numbers. Knowing the denominator does not ensure that the numbers will be

本书版权归John Wiley & Sons Inc.所有

Table 43.2 Sample metrics used in benchmarking and performance monitoring

Category	Examples of metrics	Pros	Cons	Examples of commonly used ratios
Cost/productivity	Billable tests (total, on-site, referred, inpatient, outpatient)	Data exist in laboratory information system	Dissecting out the data by the categories listed may be difficult or impossible.	Billable tests/inpatient day (inpatient discharge, outpatient visit)
Productivity	Total FTEs and total hours	Measures productive and nonproductive labor	To measure productive labor, must measure testing hours; in external benchmarking, this must be counted identically to be useful.	Billable tests/total FTE (h) Billable tests/testing FTE (h)
Cost	Total and testing labor expense; consumable expense, maintenance expense, depreciation expense	Amenable to measurement	Depreciation expense may not be broken out by the institution to the level of department or division.	Testing (total) expense/FTE (h) Consumable expense/total (on-site) billable tests Total expense/inpatient day (inpatient discharge, outpatient visit)
Workload	Inpatient days or discharges; outpatient visits	Denominator for evaluation of workload by patient type	A hospital with a large population of chronically ill patients may have aberrantly small value when days are the denominator, but discharges may provide a better comparison. Outpatient visits may be problematic because of the variation in how institutions categorize their outpatients versus physician's office patients.	Inpatient (outpatient, nonpatient) billable tests/total billable tests Billable tests/inpatient day (inpatient discharge, outpatient visit)
Quality	Corrected results, amended reports	Data readily accessible in laboratory information system	Risk, albeit small, of discouraging necessary corrections or amendments if excessive focus is placed on reducing the number instead of addressing underlying issues.	Corrected results/total results, amended reports/total reports
Quality	Near-miss reports in incident reporting system	Data readily accessible in laboratory or institutional incident reporting system	Subject to variation in recognition if not clearly defined for reporting purposes	Near misses/total incidents reported

meaningful, but the numerator alone will be useful only rarely. The two main types of useful financial and operational ratios may be characterized as cost ratios and productivity ratios, and in both of these types, the most valid denominator is a unit of service such as the "billable test" (which describes any procedure for which there is a Current Procedural Terminology [CPT] code and for which a client could have been billed).

Quality indicators likewise center on ratios and in aggregate may span the total testing process from preanalytical to postanalytical. The denominator in quality indicators generally reflects the number of opportunities for error and varies across phases and types of testing. An example is the sigma metric (14).

Effects of the COVID-19 Pandemic Render Many Data from 2020–2021 Unhelpful for Comparisons

The myriad effects of the COVID-19 pandemic have included significant disruptions to clinical laboratories' typical operations, especially in time periods characterized by surges in the infection rate. Volumes for different types of testing changed significantly; tests for SARS-CoV-2 and tests used in managing patients with COVID-19 (e.g., blood gases) increased during surges, while many other types of testing were ordered less frequently (15, 16). Laboratory staffing was affected both by organizational responses to changes in admission and testing volumes and by the direct effect of employee illness, and this has likely decreased nonmandatory data collection and analysis activities during surges. These factors render many data from 2020–2021 nonrepresentative and may have adversely affected data quality for some measures (17). While data from affected time periods need not be ignored or discarded, caution is warranted in their use (e.g., as benchmarks) and in the interpretation of data series (e.g., for performance monitoring) that include them.

Measuring Laboratory Performance in the Broader Clinical Setting

The goal of measuring and improving clinical laboratory performance is to improve the quality, safety, and value of

本书版权归John Wiley & Sons Inc.所有

medical care provided to patients and to improve the health of the population the laboratory serves. Most commonly employed laboratory benchmarking and performance monitoring techniques and indicators relate more directly to internal laboratory processes than to patient or population outcomes, however (18). Changes in payment models and policies, as well as in accreditation standards, will require laboratory directors and managers to think more broadly about appropriate measures of laboratory performance.

Assessments for Patient Safety

Fundamental to laboratory practice, as to all healthcare, is the avoidance of harm to patients. Monitoring of internal laboratory practices, while important for maintenance and improvement of quality in the analytical phase of testing, has been criticized at times for not being sufficiently connected to the aim of improving patient safety (9). This apparent disconnect has prompted greater attention to benchmarking and performance monitoring in the preanalytical and postanalytical phases, with indicators including rates of (i) use of positive patient identification, (ii) mislabeling of specimens, and (iii) documented successful critical value notification (19).

Effect of Value-Based Payment Models (and Other Contemporary Influences)

The move toward value-based payment models is well under way in the American healthcare industry. This will even more closely tie the financial performance of the laboratory to that of the physicians and hospitals with which it works to manage the care of a population. The expansion of the accountable care organization (ACO) model, together with the ongoing trends toward decreased overall reimbursement for specialty care (including laboratory services) and toward performance-based payment, will likely spur greater collaboration among laboratories, clinicians, and hospitals to enhance the value (outcomes relative to costs [20]) of the care they provide. Incentives to document laboratory contributions to value will be considerable; devising manageable ways to quantify such contributions will be no small feat, however. How much of an observed change in inpatient length of stay, for example, is attributable to a change in laboratory practice (e.g., results reporting in a timelier fashion) versus any of the myriad changes elsewhere in the system in each period is very difficult to determine with certainty.

Some consolation may be taken in the fact that devising appropriate measures is problematic not only for laboratory managers, but also for institutional leaders. Lee has recently described an initiative to define outcome measures from the patient's perspective, as these will enable the organization to enhance the value provided to patients (21). Even once such measures are identified, though, novel means for data collection will have to be devised, as some measures, such as "days spent at home during the first 90 days after a stroke" are not as readily assessed as more traditional figures, such as "30-day readmission rate." As organizations strive to improve the value of the healthcare they provide, more patient-oriented measures are likely to be embraced, and laboratory managers will need to determine how their laboratories can best support institutional efforts to meet performance goals with respect to outcomes important to patients. Given an appropriate culture of collaboration, broader institutional measures such as these—summary measures, if you will—may have a unifying effect on organizational units, including the laboratory, akin to that noted above under interpretation of performance-monitoring data.

Linkage of Payment to Measures of Quality

Payors are increasingly attempting to link payment to the meeting of quality standards, and this has resulted in the possibility of reimbursement for nonlaboratory providers being directly influenced by appropriate use of laboratory resources. CMS has administered quality initiatives linked to reimbursement for over a decade; earlier programs included the Physician Quality Reporting System (PQRS), a program in which payments to physicians for care provided to Medicare beneficiaries were adjusted to promote reporting of quality data (22). While certain quality measures can influence pathologists' reimbursement, laboratory-related measures of quality that influence other physicians' payments have included the percentage of patients with chronic hepatitis C who have quantitative HCV RNA testing 12 weeks after initiation of antiviral therapy, as well as the percentage of patients with chronic lymphocytic leukemia who have baseline flow cytometry testing. The 2015 Medicare Access and CHIP Reauthorization Act (MACRA) replaced earlier CMS programs such as PQRS with the Quality Payment Program (QPP), which includes the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) tracks. Pathologists who are qualified APM participants are incentivized to reach thresholds for payment and patients under their APMs, while all others receive positive or negative payment adjustments based on their scores that integrate performance on quality and improvement activity measures (23, 24).

Laboratory-Related Standards in Broader Accreditation Programs

Accreditation programs for clinical programs within hospitals or healthcare delivery systems increasingly incorporate standards pertaining to laboratory performance, particularly with respect to the reporting of results. For example, many hospitals with cancer programs seek accreditation by the American College of Surgeons

本书版权归John Wiley & Sons Inc.所有

Commission on Cancer (CoC). To ensure that the information needed for developing an individualized cancer treatment plan is available to the patient's physician(s), Standard 5.1 of the 2020 CoC standards requires that "Ninety percent of the eligible cancer pathology reports are structured using synoptic reporting format as defined by the College of American Pathologists (CAP) cancer protocols, including containing all core data elements within the synoptic format" (25). Standards pertaining to other sections of the laboratory are similarly promulgated by accreditation bodies that are not primarily laboratory focused; examples include cellular therapy accreditation standards for hematopoietic progenitor cell transplant programs (26). The need for awareness of new or evolving laboratory-related standards in such programs is yet one more good reason for laboratory managers to be in regular communication with colleagues elsewhere in the institution.

The Unattained Ideal: A Global Laboratory Benchmarking Scorecard Spanning Cost, Quality, and Operational Measures

Even in a laboratory with a robust QMS, extensive financial reporting capabilities, and numerous reliable operational metrics, there may not be a single document that rolls up results, annually or otherwise, from the various domains to provide a global view of the laboratory's performance. Some laboratories or departments of pathology and laboratory medicine produce an annual report that summarizes happenings from the prior year and includes data of various sorts, but these often focus on internal trends (i.e., performance monitoring) with fewer references to external benchmarks.

Many barriers would need to be overcome to facilitate the creation of a global laboratory benchmarking scorecard spanning multiple domains of performance. Perceived barriers include:

- Networking ability
- Interoperability and data sharing among laboratories
- Benchmarks that encompass all three phases of testing (preanalytic, analytic, postanalytic)
- More benchmarking in domains of quality desired by laboratories
- Relative lack of externally published information
- Measuring laboratory performance from the perspective of the customer (patients, but also clients)

Potential solutions to overcoming these barriers remain elusive, but we wonder if the proficiency testing model could be expanded to incorporate external quality assessment among all phases of the testing process as a first step toward a global scorecard.

SUMMARY

Determining which improvements in technology, which computer systems, and what test mix will improve patient outcomes, provide the best quality, and meet financial objectives is an overwhelming task. With benchmarking, we have a method to measure performance and improve our ability to meet our goals, which typically include improved health, high quality, and an overall increase in efficiency. Accreditation and licensure focus primarily on improving health and increasing quality; we can apply benchmarking and performance monitoring to improve efficiency. Most hospital laboratories operate on a 24 hours per day, 7 days per week schedule, resulting in a high fixed cost structure in an environment of declining reimbursements and continuing shortages of personnel. Continuous and significant gains in productivity and efficiency are required to do more with less each year. Changes in the financial and regulatory environment will necessitate a broader conception of what it means to measure laboratory performance.

KEY POINTS

- A creative approach to benchmarking allows you to find measures of industry-leading performance in almost any area.
- Groups can arrive at consensus on critical processes that must be improved or maintained above certain thresholds for benchmarking and for performance monitoring.
- It is important to clearly define measures that are appropriate to the task and that are realistic in terms of data and resource availability.
- The most effective benchmarks address either a specific concern (such as the Q-Probes and Q-Tracks) or overall concerns reflecting performance in summary measures.
- Validation of high-level benchmarks often yields more information about overall performance.
- If the resources are available, it is optimal to participate in both internal performance monitoring and external benchmarking activities.
- Review of performance against benchmarks frequently identifies areas in which additional interventions could yield improvements in performance.
- Networking and membership in leading laboratory organizations are excellent ways to find relevant benchmarks.

本书版权归John Wiley & Sons Inc.所有

GLOSSARY

Accountable care organization (ACO) An organization composed of physicians and other clinicians, hospitals, and other providers of healthcare services who collaborate in an effort to provide more coordinated, higher quality care at a lower cost than the fee-for-service model; can be important players in markets with higher prevalence of value-based reimbursement approaches.

Accreditation Approval, for a limited time, of an institution or program based on a review of the institution or program by one or more independent examiners who determine that specific requirements or standards have been met.

Accrediting agencies Organizations that validate the ability of a laboratory to perform laboratory testing. In the United States, the federal government is charged by statute (CLIA '67 and CLIA '88) with the task of regulating diagnostic laboratory testing on human patients. CMS is charged by Congress with the task of developing and implementing regulations. CMS can "deem" other organizations to issue accreditation if their standards meet or exceed those of CMS. Testing of animals and research subjects is not covered by these regulations.

Advanced alternative payment model (APM) A specific type of payment approach defined by CMS that not only provides additional incentive payments for providing care that is high quality and cost-efficient, but also, if certain thresholds are cleared, may provide enhanced reimbursement and decreased reporting requirements for subsequent years. May be focused on specific patient populations or clinical conditions.

Benchmark A standard against which performance is measured. The standard typically represents performance that is considered the best in the field or the gold standard of performance. Various internal, external, industry-wide, and nonindustry performance measures may all be used as benchmarks.

Benchmarking Comparing your own performance against a standard—usually representing the gold standard or best practice for similar activities—and engaging in processes to improve performance against the chosen standard.

Billable test Usually defined in benchmarking parlance as a test for which there is a CPT code and that could, therefore, be billed to Medicare or other payors.

Billed test A test that is billed to an insurer or client. *Billable* test, not *billed* test, is the parameter usually preferred by benchmarking programs because institutions vary in what they bill. The most frequently used denominator for cost and productivity. May also be used as the numerator when analyzing work by patient population.

Centers for Medicare and Medicaid Services (CMS) The federal agency (formerly known as the Health Care Financing Administration, or HCFA) within the United States Department of Health and Human Services that administers the Medicare and Medicaid programs.

Clinical Laboratory Improvement Act of 1967 (CLIA '67) Established the initial authority to regulate laboratories in the United States. It was superseded by CLIA '88.

Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) Currently the governing authority for regulations regarding function of all laboratories that perform clinical testing of human specimens in the United States.

Clinical Laboratory Management Association (CLMA) Professional organization concerned with all aspects of laboratory management. Many local chapters have been organized.

College of American Pathologists (CAP) Professional organization of board-certified pathologists that plays a leading role in laboratory accreditation and proficiency testing.

Competitive benchmarking Comparing your own performance against that of competitors in the same industry or market, rather than focusing primarily on gold standards or best practices as standards for performance.

Current Procedural Terminology (CPT) A uniform set of codes used to describe and report medical services and procedures performed, especially to governmental and private payors for reimbursement.

Data mining Searching of data (usually large quantities) for underlying patterns or other information.

Deemed authority The approval by CMS, as agent for the federal government, of another organization to represent the government in accrediting clinical laboratories that evaluate human specimens. Deemed status is time limited, so each deemed organization must document that it holds a valid certificate. The standards of each deemed organization must be reviewed and accepted by CMS.

External benchmarking Benchmarking activities that include comparison of the performance of one laboratory with that of its peers. The comparisons may be made through an external organization or by informal arrangement among laboratories.

Full-time employee (or full-time equivalent) (FTE) A measure of the workforce. Part-time employees are counted as fractions of an FTE. FTEs are calculated by dividing total paid hours by 2,080 (52 weeks × 40 h per week).

Internal benchmarking Benchmarking activities comparing performance of subdivisions of a single organization, intended to facilitate dissemination of best practices across business units.

Medicare Access and CHIP Reauthorization Act (MACRA) A bill signed into law in 2015 that created the Quality Payment Program (QPP) and repealed the Sustainable Growth Rate formula that, under the Balanced Budget Act of 1997, was intended to rein in the growth of total Medicare expenditures for physician services.

Merit-based Incentive Payment System (MIPS) A pathway under the CMS Quality Payment Program in which payments for professional services are adjusted based on results across performance categories that relate to quality and cost of care provided, process improvements, and use of certified electronic health record systems.

本书版权归John Wiley & Sons Inc.所有

Nonproductive FTE Commonly used to describe those personnel who are not involved directly in the generation of test results. This category includes supervisory personnel, support personnel (marketing, customer service, washroom, etc.), and the portion of line personnel devoted to activities such as quality control and maintenance.

Paid hours The number of employee hours actually paid for by the laboratory. It includes those worked hours and those that are due to employees as part of a benefit package (sick leave, vacation, etc.).

Performance monitoring The tracking of performance over time.

Productive FTE Usually employed to define those laboratory workers who directly produce test results. In practice, defining who these individuals (or parts of individuals) are becomes very difficult and even more difficult to calculate. For instance, do you count those people who enter the specimen into the system or enter results into the information system?

Quality assurance A systematic process of assessing and improving processes to ensure that laboratory services are of high quality.

Quality improvement (QI) Involves outcomes, results, ends, and information rather than just concerns with specific processes. Whereas quality assurance is focused on providing a quality test result, QI is concerned with improving the entire process so that the results are more accurate, more timely, and presented in a more useful and informative manner to the clinician. Thus, QI is concerned with all aspects of testing, including the preanalytic, analytic, and postanalytic phases.

Quality management system (QMS) A documented set of processes, policies, and procedures for assessing and improving the quality of laboratory services and ensuring that customers' requirements are met.

Quality Payment Program (QPP) Program through which CMS seeks to incentivize provision of high-quality, high-value health care services to Medicare beneficiaries through performance-based payment adjustments or customized payment approaches.

Six Sigma An approach to improving quality that involves measuring defects or adverse events per opportunity. This approach could be viewed as a variation on benchmarking.

Skill mix The mixture of personnel with varying degrees of training, education, and certification.

Summary measure A variable that integrates multiple underlying parameters: here, a simple number (e.g., cost per billable test) used to broadly assess laboratory financial performance.

Testing FTE See Productive FTE.

The Joint Commission (TJC) A nonprofit organization that accredits numerous U.S. healthcare organizations. TJC accreditation is included by many states as a condition for participation in governmental health care reimbursement programs.

Total FTE The total number of FTEs employed in the laboratory, regardless of their duties.

Total quality management An approach to integrating multiple activities revolving around QI.

Unit of service (UOS) The denominator in ratios used to analyze cost or productivity. The most used UOS is the billable test.

Worked hours The number of hours worked by employees (cf. paid hours).

Workload recording A means of measuring laboratory output and, consequently, productivity by tallying individual components of laboratory test performance quantitatively. The most prominent national program that provided norms for quantifying effort was eventually abandoned because of the difficulty in maintaining a viable system.

ACKNOWLEDGMENTS

The authors wish to acknowledge the contributions of Lionelle D. Wells, Washington C. Winn, Jr., and Ronald J. Bryant to chapters 48 and 50 in the Second Edition of this book. Portions of their text are preserved.

REFERENCES

1. **Rudolf J.** 2020. Benchmarking: a promising practice for lab stewardship toolkits. *Clin Lab News*. https://www.aacc.org/cln/articles/2020/april/benchmarking-a-promising-practice-for-lab-stewardship-toolkits. Accessed 16 February 2023.

2. **Valenstein P**, **Schneider F**. 2008. Benchmarking laboratory quality. *Lab Med* **39**:108–112.

3. **National Institutes of Health Office of Research Services**. 2023. Benchmarking. https://ors.od.nih.gov/OD/OQM/benchmarking/Pages/benchmarking.aspx. Accessed 16 February 2023.

4. **Taylor B**. 2007. Beyond benchmarking: why copy the competition? *Harvard Business Review Blog Network*. http://blogs.hbr.org/taylor/2007/10/beyond_benchmarking_why_copy_t.html. Accessed 16 February 2023.

5. **Heatherley SS**. 1997. Key performance indicators to assess laboratory operations. Benchmarking for survival. *Clin Lab Manage Rev* **11**:164–170.

6. **Portugal B.** 1993. Benchmarking hospital laboratory financial and operational performance. *Hosp Technol Ser* **12**:1–21.

7. **Howanitz PJ**, **Perrotta PL**, **Bashleben CP**, **Meier FA**, **Ramsey GE**, **Massie LW**, **Zimmerman RL**, **Karcher DS**. 2014. Twenty-five years of accomplishments of the College of American Pathologists Q-Probes program for clinical pathology. *Arch Pathol Lab Med* **138**:1141–1149.

8. **Procop GW**, **Nelson SK**, **Blond BJ**, **Souers RJ**, **Massie LW**. 2020. The impact of transit times on the detection of bacterial pathogens in blood cultures: a College of American Pathologists Q-Probes study of 36 institutions. *Arch Pathol Lab Med* **144**:564–571.

9. **Sciacovelli L**, **Lippi G**, **Sumarac Z**, **West J**, **Garcia Del Pino Castro I**, **Furtado Vieira K**, **Ivanov A**, **Plebani M**, **Working Group**

本书版权归John Wiley & Sons Inc.所有

"Laboratory Errors and Patient Safety" of International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). 2017. Quality indicators in laboratory medicine: the status of the progress of IFCC Working Group "Laboratory Errors and Patient Safety" project. *Clin Chem Lab Med* **55**:348–357.

10. AT&T Quality Steering Committee. 1992. *Benchmarking: Focus on World-Class Practices*. AT&T Customer Information Center, Indianapolis, IN.

11. Boxwell RJ. 1994. *Benchmarking for Competitive Advantage*. McGraw-Hill, Inc, Cambridge, MA.

12. Chiozza ML, Ponzetti C. 2009. FMEA: a model for reducing medical errors. *Clin Chim Acta* **404**:75–78.

13. Spear SJ, Bowen HK. 1999. Decoding the DNA of the Toyota production system. *Harv Bus Rev* (September-October):97–106.

14. Messinger BL, Rogers DN, Hawker CD. 2019. Automation and process re-engineering work together to achieve Six Sigma quality: a 27-year history of continuous improvement. *Lab Med* **50**:e23–e35.

15. Durant TJS, Peaper DR, Ferguson D, Schulz WL. 2020. Impact of COVID-19 pandemic on laboratory utilization. *J Appl Lab Med* **5**:1194–1205.

16. Lin DC, Parakati I, Haymond S. 2022. The impact of COVID-19 on laboratory test utilization at a pediatric medical center. *J Appl Lab Med* **7**:1076–1087.

17. Silungwe A. 2020. *Benchmarking and Rebasing National Accounts*. International Monetary Fund (IMF). https://www.imf.org/-/media/Files/Publications/covid19-special-notes/en-special-series-on-covid-19-benchmarking-and-rebasing-national-accounts.ashx. Accessed 16 February 2023.

18. Price CP. 2005. Benchmarking in laboratory medicine: are we measuring the right outcomes? *Benchmarking (Bradf)* **12**:449–466.

19. Meier FA, Badrick TC, Sikaris KA. 2018. What's to be done about laboratory quality? Process indicators, laboratory stewardship, the outcomes problem, risk assessment, and economic value: responding to contemporary global challenges. *Am J Clin Pathol* **149**:186–196.

20. Porter ME. 2010. What is value in health care? *N Engl J Med* **363**:2477–2481.

21. Lee TH. 2012. Care redesign—a path forward for providers. *N Engl J Med* **367**:466–472.

22. Centers for Medicare & Medicaid Services. 2023. CMS measures inventory. https://www.cms.gov/medicare/quality/measures/cms-measures-inventory. Accessed 10 September 2023.

23. Polk L. 2021. 2022 MIPS final rule changes and 8 key takeaways for pathology practices. https://www.xifin.com/resources/blog/202112/2022-mips-final-rule-changes-and-8-key-takeaways-pathology-practices. Accessed 16 February 2023.

24. Centers for Medicare and Medicaid Services (CMS). 2021. Quality payment program. https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program. Accessed 16 February 2023.

25. American College of Surgeons Commission on Cancer. 2022. *Optimal Resources for Cancer Care. 2020 Standards*. Updated April 2022. American College of Surgeons, Chicago, IL.

26. Foundation for the Accreditation of Cellular Therapy (FACT). 2023. Hematopoietic cell therapy standards. https://www.factglobal.org/standards/hct-standards/. Accessed 10 September 2023.

本书版权归John Wiley & Sons Inc.所有

APPENDIX 43.1 Performance characteristics of four laboratories

NOTES

Start by examining the characteristics of the four laboratories (rows 51–64). Note that the "numbers" in rows 4–48 serve only as clues to which issues require deeper analysis. Laboratories A and B are those for which comparisons are most legitimate. It is more difficult to compare either of these laboratories to laboratory C, and laboratory D is in quite a different category from the other three.

1. The test volume of all four laboratories is similar (B > D > C > A).
2. Laboratories A and B are the most complex of the group.
   - Both are primary university-affiliated laboratories with large pathology residency programs, a full range of services, and a small number of referred tests.
   - Blood expense is correspondingly high. Laboratory B appears to be the most complex of the group.
3. Laboratory C is also a hospital laboratory but with a more restricted range of services.
   - It is in a teaching hospital but is an affiliate with a small number of pathology residents.
4. Laboratory D is an independent laboratory with a clientele that consists entirely of outpatients and nonpatients.
   - The menu of offered services appears to consist of simple tests, as a very small percentage of tests are referred, and the laboratory does not contain scientifically complex divisions.
   - The nonpatient tests could represent work done for physicians who bill as a group or could represent work from other institutions, such as nursing homes and other chronic care facilities.
5. Compare laboratories A and B, the two primary university laboratories.
   - They are similar in most parameters (rows 51–64), but laboratory B performs a larger volume of tests (row 4).
   - Both laboratories do most of their testing on-site (row 27) and send only a small fraction of tests to a referral laboratory (row 28).
   - The two laboratories differ in the origin of their testing (rows 29–31); most business for laboratory A is from its outpatient business, whereas inpatient work comprises most of laboratory B's business. Nonpatient tests account for a minority of business for both laboratories A and B, though they comprise a slightly higher percentage for laboratory A.
   - Productivity for the two laboratories is similar, whether measured by productive paid hours, total paid hours, or FTEs (rows 32–36, 46–48).
   - Consumable expenses are similar in the two laboratories (row 44).
   - Referred test expense per billed test is greater for laboratory B than for laboratory A (row 45), suggesting that the tests sent out by laboratory B are more time-consuming, use more expensive reagents, or are less susceptible to competition in the marketplace. Alternatively, laboratory A may use a less expensive reference laboratory or have negotiated a better contract than laboratory B.
   - Although productivity, as measured by hours, is similar between the two laboratories, labor expenses are very different (rows 42–43). There are several explanations for the difference; the explanation may be due to a single factor or a combination of the following:
   - The ratio of worked hours to paid hours is higher for laboratory B (row 37), suggesting that the benefits are more generous in laboratory A than in laboratory B. Alternatively, personnel in laboratory A may have achieved better benefits because of a longer average length of service.
   - The salaries in laboratory A may be higher than in laboratory B because of regional differences, competitive factors in the local marketplace, or better negotiated contracts if the workforce is unionized. Once again, if the workers in laboratory A have greater length of service, their salaries may be higher on average than those in laboratory B.
   - The skill mix utilized in the two laboratories may be different. If laboratory B uses more technical assistants and medical technicians, whereas laboratory A uses more medical technologists, labor costs would be higher in laboratory A. Ultimately, all the possible differences in labor costs might be acceptable to the management of each laboratory because of other perceived advantages.
   - The utilization of tests for inpatients is more efficient in laboratory A than in laboratory B (rows 39–40). Once again, there are several explanations:
     - Laboratory A may have better control over the utilization of laboratory services than does laboratory B.
     - There may be more chronic care patients, who require less intensive laboratory support, in the institution served by laboratory A (less likely as an explanation, however, as the phenomenon is observed whether the denominator is inpatient days or discharges).
     - The acuity of illness of patients served by laboratory B may be greater than that of patients served by laboratory A (more trauma, more transplants, etc.). To some extent, this variable could be analyzed by including objective characterizations of the patient population, such as the Medicare case mix index.</BL-2>
   - The reverse situation occurs with outpatient tests, where laboratory B appears to function better (row 41). This parameter is more difficult to assess, however, because of the difficulties involved in determining outpatient visits objectively and comparatively.
6. Compare laboratory C with laboratories A and B.
   - Laboratory C is a university-affiliated laboratory with a pathology residency program but only a small number of residents (rows 53–54).

本书版权归John Wiley & Sons Inc.所有

APPENDIX 43.1 Performance characteristics of four laboratories *(continued)*

- Laboratory C serves inpatients primarily (rows 7–9, 29–31); notably, there are no nonpatient tests.
- Laboratory C sends a relatively large percentage of its tests to a reference laboratory (rows 5–6, 27–28), compatible with a general hospital laboratory.
- Productivity for laboratory C is, not surprisingly for a less complicated laboratory, better than for laboratories A and B (rows 32–33, 35–36). Interestingly, productivity looks less different when only productive labor is compared (row 32), because laboratory C has few nonproductive personnel (more of the employees in that laboratory are actually involved in turning out results; fewer are in managerial or support services) (row 34).
- All costs are lower for laboratory C than for laboratories A and B (rows 42–44). The fact that testing (productive) costs are also lower suggests that salaries and/or benefits may be lower in this laboratory (row 42). This interpretation is compatible with the observation that the ratio of productive to total personnel is higher in laboratory C than in either laboratory A or B (row 34).
- Although the number of tests sent to a reference laboratory from laboratory C is higher than for either laboratory A or B (rows 6 and 28), the cost of referral testing is less on a unit basis (row 45). The explanation for this phenomenon may be that laboratory C is performing less complicated or sophisticated testing in general and is also sending less complicated tests to the reference laboratory than are laboratories A and B. In fact, laboratory A or B could be the reference laboratory for laboratory C.
- Utilization of laboratory resources for inpatients is higher in laboratory C's institution than in the two primary university-affiliated laboratories (rows 39–40). The difference is greater when tests per discharge are compared than when the comparison is by tests per inpatient day. This situation suggests a greater proportion of chronic care patients at the institution served by laboratory C and provides a potential target for improvement of laboratory utilization and costs. Outpatient utilization appears similar in the three institutions (row 41).

7. Comparison of laboratory D with laboratories A, B, and C:
   - Laboratory D is very different from any of the other three laboratories (rows 51–64). It serves outpatients and nonpatients exclusively (rows 7–9, 29–31). The nonpatients may represent patients of physicians with whom the laboratory has a contract or patients in chronic care facilities such as nursing homes. Data for outpatient visits are not given (row 12), suggesting that the laboratory does not have access to the records of those patients who are classified as outpatients. Not surprisingly, there is no blood expense (row 24). If the data were broken out in more detail, you might expect to find a high percentage of simple automated chemistry and hematology tests in the workload of Laboratory D.
   - Despite the large volume of tests, very few of laboratory D's tests are sent to a reference laboratory (rows 6 and 28). The cost of these referred tests is low (row 45), suggesting that they are uncomplicated.
   - All major costs are less for laboratory D than the other three (rows 18–22, 42–44), again reflecting the outpatient nature of the laboratory.
   - Some clues as to the reasons for lower labor costs can be found in the high ratios of worked to paid hours and of productive to total FTEs (rows 34 and 37).

本书版权归John Wiley & Sons Inc.所有

APPENDIX 43.1 Performance characteristics of four laboratories *(continued)*

	PARAMETER	Laboratory A	Laboratory B	Laboratory C	Laboratory D
4	Total Billable Tests (BT)	788,674	1,014,980	878,932	956,873
5	On-Site Billable Tests	777,448	1,009,087	786,453	954,417
6	Referred Tests	11,226	5,893	92,479	2,456
7	Inpatient Billable Tests	257,896	573,217	784,921	0
8	Outpatient Billable Tests	466,916	389,529	94,011	750,275
9	Nonpatient Billable Tests	63,862	52,234	0	204,142
10	Hospital Inpatient Days	28,656	47,504	62,879	N/A
11	Hospital Inpatient Discharges	5,037	8,023	7,543	N/A
12	Outpatient Visits	57,233	74,167	18,802	N/A
13	Productive Paid Hours	61,269	75,421	60,720	63,191
14	Total Laboratory Worked Hours	90,357	116,902	82,406	77,409
15	Total Laboratory Paid Hours	100,662	125,701	86,473	78,989
16	Calculated Productive FTEs	117.83	145.04	116.77	121.52
17	Calculated Total FTEs	193.58	241.73	166.29	151.90
18	Productive Labor Expense ($)	1,569,131	1,552,929	971,522	884,677
19	Total Labor Expense ($)	2,348,641	2,352,923	1,387,888	1,105,846
20	Consumable Expense ($)	1,074,239	1,418,697	983,066	1,049,859
21	Equipment Maintenance and Repair ($)	68,429	67,707	54,987	32,343
22	Equipment Depreciation ($)	96,952	121,494	76,354	54,985
23	Referred Test Expense ($)	154,406	136,750	801,793	12,771
24	Blood Expense ($)	604,654	926,001	345,890	0
25					
26	**RATIOS**				
27	On-Site BT as % of Total BT	98.58	99.42	89.48	99.74
28	Referred Tests as % of Total BT	1.42	0.58	10.52	0.26
29	Inpatient BT as % of Total BT	32.70	56.48	89.30	0.00
30	Outpatient BT as % of Total BT	59.20	38.38	10.70	78.41
31	Nonpatient BT as % of Total BT	8.10	5.15	0.00	21.33
32	On-Site BT/Productive FTE	6,598	6,957	6,735	7,854
33	On-Site BT/Total FTE	4,016	4,174	4,729	6,283
34	Productive FTE/Total FTE	0.61	0.60	0.70	0.80
35	On-Site BT/Total Worked Hours	8.60	8.63	9.54	12.33
36	On-Site BT/Total Paid Hours	7.72	8.03	9.09	12.08
37	Total Worked Hours/Total Paid Hours	0.90	0.93	0.95	0.98
38	On-Site BT/Total BT	0.99	0.99	0.89	>0.99
39	Inpatient BT/Day	9.00	12.07	12.48	N/A
40	Inpatient BT/Discharge	51.20	71.45	104.06	N/A
41	Outpatient BT/Outpatient Visit	8.16	5.25	5.00	N/A
42	Productive Labor Expense/On-Site BT ($)	2.02	1.54	1.24	0.93
43	Total Labor Expense/On-Site BT ($)	3.02	2.33	1.76	1.16
44	Consumable Expense/On-Site BT ($)	1.38	1.41	1.25	1.10
45	Referred Test Expense/Referred BT ($)	13.75	23.21	8.67	5.20
46	Testing Paid Hours/On-Site BT	0.08	0.07	0.08	0.07
47	Worked Hours/On-Site BT	0.12	0.12	0.10	0.08
48	Paid Hours/On-Site BT	0.13	0.12	0.11	0.08
49					

本书版权归John Wiley & Sons Inc.所有

APPENDIX 43.1 Performance characteristics of four laboratories *(continued)*

	PARAMETER	Laboratory A	Laboratory B	Laboratory C	Laboratory D
50	**LABORATORY CHARACTERISTICS**				
51	University Affiliated Laboratory	Yes	Yes	Yes	No
52	Primary University Laboratory	Yes	Yes	No	No
53	Pathology Residency Program	Yes	Yes	Yes	No
54	Number of Pathology Residents	14	25	4	0
55	Surgical Pathology	Yes	Yes	Yes	No
56	Cytopathology	Yes	Yes	Yes	No
57	Cytogenetics	Yes	Yes	No	No
58	Autopsy	Yes	Yes	Yes	No
59	Electron Microscopy	Yes	Yes	No	No
60	Molecular Diagnostics Laboratory	No	Yes	No	No
61	Courier Service	Yes	Yes	No	Yes
62	Marketing Personnel	Yes	Yes	No	Yes
63	Customer Service Personnel	Yes	Yes	Yes	Yes
64	Dedicated Compliance Personnel	Yes	Yes	Yes	Yes

本书版权归John Wiley & Sons Inc.所有

44

Introduction

Evaluating Potential and Real Problems
Clinical Relevance • Cost-Effectiveness Analysis, Cost-Benefit Analysis, and Cost-Utility Analysis

Documenting the Extent of the Problem
Literature Review • Centralized Studies • Local Data

Laboratory-Based Approaches to Control
Newsletters • Policy Changes • Personal and *Ad Hoc* Communication • EMR-Based Limits and Restrictions on Test Ordering • EMR-Based Feedback in Reports

Institution-Based Approaches to Control
Working with Providers • Formal Protocols Validated by Provider Leadership • The Concept of a Test Formulary • Using Major Events To Effect Change

What Works and Doesn't Work: How To Take the First Steps

Putting It All Together
Base Policy Approaches and EMR-Based Controls on Evidence-Based Medicine • Track Results • The Plan, Do, Study, Act Model • The Future: Better Teaching and Training

SUMMARY

KEY POINTS

GLOSSARY

REFERENCES

Test Utilization and Clinical Relevance

Michael L. Wilson, Gary W. Procop, and L. Barth Reller

OBJECTIVES

To become familiar with the concepts of clinical relevance and cost-effectiveness and how they are related

To learn how to document the extent of the problem of laboratory test utilization, including relevant sources of information

To learn laboratory-based approaches to the control of laboratory test utilization

To learn institution-based approaches to the control of laboratory test utilization

To learn one approach for the implementation of change in a patient care setting (McLaughlin's approach)

To learn one approach for integrating evidence-based medicine with computer-based systems for controlling laboratory test utilization

Managing upstream demand, downstream interpretation of laboratory results, and subsequent appropriate action through close relationships between laboratorians and clinicians remains a crucial issue of the laboratory testing process.

Mario Plebani and Mauro Panteghini (1)

Diagnostic testing is an essential component of healthcare systems. In some settings, mostly in low-income and middle-income countries but also in some areas in high-income countries (HIC), access to diagnostic testing is inequitable or, in many cases, lacking altogether. In other areas, mostly in HIC, too much diagnostic testing occurs; the result is increased healthcare costs without improving health of populations. Therefore, the challenge for clinical laboratories in all settings is to offer tests that provide the most benefit on health outcomes, doing so in a timely manner, and at a level of expense affordable by patients and healthcare systems—or, put another way, the most value.

In previous editions, this chapter focused on limiting/controlling test utilization, mostly because of the need to help control rapidly increasing healthcare costs that health systems were facing in HIC. Although this challenge remains in HIC, it is hoped that attempting to define *appropriate* test utilization (in contrast to concentrating on overutilization), along with mechanisms to implement controls on inappropriate test utilization, there will also be benefits to countries that are trying to increase and improve access to diagnostics. This chapter once again will use clinical

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch44.

本书版权归John Wiley & Sons Inc.所有

microbiology as the exemplar for defining and guiding appropriate test utilization.

Clinical microbiology laboratories have unique challenges. They perform tests to aid in the diagnosis of diverse infectious diseases, help guide therapy for those diseases, help control and prevent infection in healthcare settings, and educate and train professionals.

This mission—providing high-quality, cost-effective laboratory testing covering a number of subdisciplines—has become even more challenging in recent years because of the emphasis on cost control in healthcare, the introduction of new (and often more expensive) diagnostic technologies, and increasing regulations. Thus, laboratories must maintain quality while expanding services with ever-diminishing resources. In the past, laboratories could control costs by using traditional management techniques, yet most laboratories exploited this technique to its fullest many years ago (2). One approach to solving this dilemma is for laboratories to limit testing to those assays that are both clinically relevant as well as cost-effective. For most of the recent past, there were more—and stronger—reasons to perform tests than there were reasons to limit test utilization. Only in the past few years have economic incentives for limiting utilization coincided with medical incentives for improving clinical relevance. The alignment of these incentives affords clinical laboratories an opportunity to eliminate unnecessary tests, offer only tests known to be clinically relevant, and use information technology to facilitate implementation of these changes.

The purpose of this chapter is to provide the reader with a strategy for making changes in laboratory utilization that are based on the clinical relevance of tests. The information contained herein is not meant to be a theoretical approach to change. Rather, it provides specific guidance for dealing with political realities and other impediments to making change. Although this book covers clinical laboratory management in general, the information that has been selected for this chapter deals primarily with clinical microbiology. This information was selected because some of the information and tactics were developed first and specifically for clinical microbiology laboratories. Another reason for using clinical microbiology as a paradigm for change was that attempts at changing the utilization of microbiology services can be more controversial than in other areas of the laboratory. This is because clinical microbiology tests (i) are more interpretive in nature compared with most other clinical laboratory tests, (ii) are less standardized than many other clinical laboratory tests, (iii) deal with living microorganisms that have variable phenotypic and genotypic characteristics, (iv) are often made more complicated by the presence of contaminating microbiota (i.e., flora), and (v) increasingly require awareness of host-pathogen interactions that do not need to be considered with most other laboratory tests.

Evaluating Potential and Real Problems

One can assess laboratory utilization from a number of perspectives, including financial models, staffing ratios, productivity or other benchmarks, treatment and evaluation guidelines, and so forth. The approach that is selected should correspond to what prompted the assessment. For example, if a laboratory is being reorganized to meet financial constraints, then financial models and productivity benchmarks should be guides for the assessment. If an assessment is being done because of the introduction of new diagnostic technology or the expansion of services to meet new clinical needs, then the assessment should be based on treatment and evaluation guidelines, clinical protocols, or other clinically driven considerations. Regardless of the approach taken, the one principle that must play a role in any assessment of laboratory utilization is that of clinical relevance; no test can be cost-effective, no laboratory can be efficient and productive, and no organization can provide good patient care unless laboratory testing is clinically relevant.

Clinical Relevance

Most laboratorians and providers have an idea of what is meant by the term "clinical relevance" (or the similar terms "clinical significance" and "clinical importance"). The term is not used consistently, however, because there is no standard definition, nor is there yet a quantifiable way to measure clinical relevance. This lack of objectivity should not lead to inaction. For example, there are many instances wherein standing orders are no longer clinically relevant. Even though orders may have been appropriate when first written, as the condition of the patient changed the orders became unnecessary. One simple approach is to time limit standing orders (e.g., 3 days), rather than leaving orders open *ad infinitum*. This helps to assure that laboratory testing will be made after thoughtful consideration, rather than based on a standing order, the usefulness of which may be outdated as the patient's condition evolves. As shown in Table 44.1, clinically relevant tests share certain characteristics that can be used in an audit.

Cost-Effectiveness Analysis, Cost-Benefit Analysis, and Cost-Utility Analysis

Cost-effectiveness analysis (CEA) has been defined as "the primary tool for comparing the cost of a health intervention

Table 44.1 Characteristics of clinically relevant laboratory tests

Test results can be used to initiate, modify, or terminate therapy
Test results are available in an acceptable time frame
Test sensitivity and specificity are acceptable to users
Test positive and negative predictive values are acceptable to users
Test results are easily reported to and interpreted by users

本书版权归John Wiley & Sons Inc.所有

with the expected health gains" (3) and as "a method for evaluating the health outcomes and resource costs of health interventions" (4). The method has been in use for many years and has been the subject of much discussion as a potential means of helping guide healthcare policy and allocation of resources (5). Although there is understandable confusion between the terms CEA, cost-benefit analysis (CBA), and cost-utility analysis (CUA), these terms have specific meanings and usages (3):

- CEA expresses outcomes in *natural units* (e.g., cases prevented or number of lives saved).
- CBA assigns *dollar values* to the outcomes attributable to the program.
- CUA is a specialized form of CEA that includes a *quality-of-life component* associated with morbidity using common health indices such as quality-adjusted life years and disability-adjusted life years.

Compared with CBA and CUA, CEA is:

- Less time- and resource-intensive
- Easier to understand
- More readily suited to decision making

Despite being a better type of analytical tool compared with the other two methods, CEA may not be useful as a tool to evaluate laboratory tests. Trying to determine the contribution of a laboratory test result to a natural outcome such as cases prevented or costs avoided is difficult; there are so many other variables that determine a patient-care outcome that determining the relative role and any effect of the laboratory test result may be impossible. For example, the impact of using a rapid malaria diagnostic test as part of a malaria control program depends not only on the accuracy of the test but also on convincing providers to order the test, whether providers base treatment on the test result, whether or not the treatment was appropriate, patients were compliant, the presence or absence of comorbid conditions, and the severity of the infection (6). As another example, a new test to confirm infection in critically ill patients may provide accurate and timely test results, but the variables of getting the provider to order (appropriate) therapy, the time needed to dispense and administer that therapy, pharmacokinetic variation between patients, the presence or absence of comorbid conditions, the severity of the infection, and the general health of the patient may all influence the outcome of the intervention; determining any contribution of the new test to the eventual outcome may not be possible.

Documenting the Extent of the Problem

Assessing the clinical and financial value of the tests currently performed in a laboratory, introduction of new tests, and determining whether to replace methods currently in use all require an assessment of tests in light of published information, including a review of the literature, use of centralized studies that yield benchmark information, and if necessary, use of local data.

Literature Review

The published data regarding appropriate laboratory test utilization have, until recently, focused on the issues of the relative accuracy of diagnostic methods, the clinical relevance of tests, or the cost-effectiveness of different diagnostic methods. These issues first received emphasis in the early 1970s, when controlled clinical comparisons of diagnostic laboratory methods became more common, investigators began evaluating the clinical relevance of diagnostic tests, and the issue of cost control became increasingly important. As noted by van Walraven and Naylor (7) and commented on by Lundberg (8), much of the published literature about the clinical relevance and cost-effectiveness of laboratory tests lacks the scientific rigor that characterizes evaluations of other diagnostic modalities and therapies.

These criticisms almost certainly are valid, but holding laboratory tests to the same standards as other diagnostic procedures or methods may be unrealistic—and unnecessary. There are two reasons for this. First, laboratory methods usually are used to confirm clinical impressions or to supplement clinical, radiographic, or other laboratory data. This is different from, for example, a biopsy that by itself may provide definitive diagnostic information. In other words, many laboratory tests usually do not stand alone for the purposes of making diagnoses. Second, the clinical impressions of providers play an important role in the interpretation of test results. This is because the pretest probability of a disease affects interpretation of test results. (For an example and further statistical explanation, the reader is referred to Aronson and Bor's (9) classic discussion of blood cultures, specifically the section on the influence of pretest probability on posttest probability.) Thus, while it often is possible to design controlled clinical trials of novel diagnostic methods or therapies, evaluating laboratory methods is not so straightforward.

Despite these limitations, many issues regarding laboratory tests can be studied adequately via controlled clinical trials, including product comparisons, comparison of new diagnostic tests with older methods, evaluations of the cost-effectiveness of different tests, and some evaluations of clinical relevance. Some aspects of the clinical effects of laboratory testing also can be studied adequately, such as the impact of the timeliness of result reporting (4, 10). Not surprisingly, given the interest in both cost containment in medical care and ways to improve medical outcomes, there are now hundreds of publications on test utilization. For the interested reader, there are good recent reviews of this body of literature (11, 12).

本书版权归John Wiley & Sons Inc.所有

Centralized Studies

A second type of study exists that can be useful in comparing laboratory practices among peer groups, also known as benchmarking studies. These studies differ from experimental studies in that the purpose is not to test a hypothesis, but rather to compare laboratory practices in such a way as to develop statistically valid standards against which individual laboratories can compare their relative performance. By their design they do not test clinical outcomes, so they cannot be used to determine clinical efficacy. Nonetheless, because these studies tend to involve many hospitals and laboratories, they can be used to collect large data sets about laboratory practices.

As one example, large data sets are collected as part of the College of American Pathologists (CAP) Proficiency Testing program. These data are not collected for the purpose of evaluating specific laboratory tests, but some of the results can be pooled to yield information regarding laboratory practices. In one case, the CAP Microbiology Resource Committee evaluated data regarding the utility of user-based quality control (QC) for commercial microbiological media (13). The data showed that, for a number of types of commercial media, user QC added little to manufacturer QC and therefore could be eliminated without adversely affecting quality (13). Eliminating superfluous QC not only saves money but also allows technologists to focus their time and efforts on tasks that are more beneficial to patient care.

Local Data

Making a change often requires convincing users that the change is necessary and that the decision to make the change was based on data. For the most part, data should be from published clinical trials, particularly those that meet the requirements of evidence-based medicine. In specific circumstances, as noted by McLaughlin, it helps to supplement published data with data collected locally (14). The reason for this is that many providers believe that their patients are in some way different from those elsewhere. While this may be true if one is dealing with patient populations that are specific in terms of age, gender, or ethnicity, it is not true when applied to the general population. Nonetheless, many providers do believe that their patients are different, so collecting local data can help to convince them that observations made elsewhere do apply to their patients.

Although studies performed locally are unlikely to meet the rigor required for publication of evidence-based medicine, it is unlikely that the results of local studies (if performed correctly) will differ from those performed on broader populations. As an example, in 1990, Siegel, Edelstein, and Nachamkin published a study showing that there was no yield in performing stool cultures or tests for ova and parasites after patients had been hospitalized for 3 or more days (15). This study was repeated in a number of hospitals during the next few years, culminating with a large CAP Q-Probe study that was published in 1996 (16, 17). Each of these studies yielded almost identical results as the Siegel study. There is to date no published data that the introduction of multiplex PCR testing for enteric pathogens will change the now standard approach of limiting testing for patients who have been hospitalized for 3 or more days (with the exception of testing for *Clostridioides difficile* infection).

Other examples of local data that were published and that have resulted in widespread changes in laboratory practice over the past 30 years include screening cerebrospinal fluid specimens before performing cerebrospinal fluid Venereal Disease Research Laboratory tests or mycobacterial smears and cultures (18, 19), performing nucleic acid amplification tests for the etiologic agents of viral meningoencephalitis (20), eliminating bacterial antigen tests for the diagnosis of bacterial meningitis (21, 22), and eliminating broth "backup" cultures for most tissue and fluid specimens (23). Morris et al. reviewed the cost and time savings that resulted when several of these changes were made in one laboratory; the time savings in particular were substantial (24). Test utilization changes that improve both patient outcomes and the patient experience while decreasing costs are often the changes most readily accepted by both medical and administrative professionals.

Laboratory-Based Approaches to Control

As medical care facilities have implemented computerized physician order entry (CPOE) as part of their electronic medical record (EMR) systems, it was quickly learned that these systems provide opportunities to intervene and stop unnecessary test orders before specimens are even collected. This approach saves time and money associated with unnecessary specimen collection and transportation and the actual testing. In addition, decreased phlebotomy decreases iatrogenic anemia in hospitalized patients and improves experience of patients. In addition to the ordering step in testing, a number of other laboratory-based approaches to control laboratory test utilization have been described (Table 44.2).

Newsletters

Newsletters, like all written materials, often are ineffective as a means of communication for the obvious reason that busy providers are unlikely to read them. This is particularly

Table 44.2 Laboratory-based approaches to control

Newsletters
Policy changes
Personal and *ad hoc* communication
EMR-based controls on test ordering
EMR-based feedback in reports

本书版权归John Wiley & Sons Inc.所有

true in an era where communications are via email or other electronic forms; there is a tendency for communications to get lost in the background of myriad other messages. On the other hand, newsletters have the advantage of being a dispassionate means of disseminating information. Although one should never dodge the responsibility of explaining and defending proposed changes to those who will be affected the most, there is only a finite amount of time for doing so, and it is unrealistic to meet with every provider or stakeholder, particularly in large organizations. Moreover, some individuals will not agree to proposed changes, no matter how rational or evidence-based the change is, so there is little point in trying to persuade them. When this occurs, it is better simply to announce the change as a *fait accompli*, usually as an organizational policy change.

Policy Changes

As with newsletters, policy changes are impersonal and dispassionate, with the additional advantage of having an air of authority about them, which can be useful when it is anticipated that a new policy or change in an existing policy is likely to face some opposition.

Personal and *Ad Hoc* Communication

The preceding section emphasizes the use of dispassionate and impersonal written communication as a mechanism of reducing potential opposition to making changes in laboratory practices. This is not intended to be a substitute for direct personal communication with providers as a means of explaining why changes are necessary, for receiving input from those who will be affected by the changes, and for monitoring the effect(s) of the changes. One of the first steps is to ensure support from the institutional leadership. Next, one should discuss the proposed changes at length with those who will be affected. These discussions may not reverse the decision to make the change, but merely having the discussions often ameliorates the emotional impact of the changes. In some instances, unanticipated consequences may be discovered during these conversations, and improvements to the proposed changes can be made. Approaching changes from the perspective of the provider can affect the way that the change is implemented. When the emphasis in such discussions is on the shared desire for improved patient care, change appeals to best motives of physicians and other providers (25).

EMR-Based Limits and Restrictions on Test Ordering

Since the last edition of this chapter was published, healthcare systems have moved quickly to implement EMRs as a means for handling large data sets, integrating different aspects of the cascades of care, for tracking utilization, for result reporting, and for ordering. These integrated EMRs have a number of potential functions that can be used for improving laboratory test utilization, as well as for generating the types of data needed for provider feedback. Some of these functions have been studied in different healthcare settings.

Provider feedback. There are published reports to suggest that this is an effective way to decrease test utilization, but there are concerns regarding the quality of the evidence, heterogeneity of methods, and concerns about applicability in different settings (i.e., whether the findings can be generalized) (26–28). Most importantly, it is not clear that this approach has a long-term sustainable effect (28).

Time-limited testing/duplicate testing. This is one of the easiest ways to eliminate unnecessary testing, as duplicate testing has no clinical value and preventing it is unlikely to be a controversial action. One challenge to this approach is defining which tests duplicate one another. It is obvious that the same test can be a duplicate when ordered more than once, but often two tests used for closely related purposes can be considered duplicates. A second challenge to this approach is defining the time interval beyond which a test is not considered to be a duplicate of the previous one. Despite these challenges, a number of studies have now documented the effectiveness of using rules within an EMR ordering system to decrease or eliminate duplicate testing by defining the time limits under which the same test can be ordered (29–32). This approach is likely to be one of the most straightforward, least contentious, and easiest to implement. It also avoids the problem of providers reverting to old ordering habits.

Restricting test ordering to specific providers or care units. This approach would be local one, and although it conceptually makes sense it can be more difficult to implement through an EMR ordering system. This approach has not been studied in a systematic way to determine its impact on test utilization. Because of the comparatively low number of tests that would be restricted by use of this approach, it is unlikely to have much impact on overall test utilization. It could be used to control use of select tests, however, so it could play a small but important role.

Requiring specific clinic information to order tests. Integrated EMRs have the ability to link results from one part of the system (e.g., pharmacy) with test ordering, although doing so may not be simple. This approach would be a good way to improve test quality so that tests are only ordered when specific parameters have been met. As one example, linking measurement of drug levels with dosing schedules would improve the accuracy of the measured levels, particularly when a patient is receiving a drug for which peak and/or trough levels are used to guide subsequent doses.

本书版权归John Wiley & Sons Inc.所有

Display of test charges. In one of the earliest studies of this intervention, Tierney et al. showed that computerized display of test charges for outpatients resulted in a significant decrease in test utilization. Although Bates et al. showed that a similar effect did not occur with inpatients, there were trends in that direction (33). Neither of these studies were conducted during an era of integrated EMRs. More recently, several studies have shown a positive effect at reducing test utilization based on display of test charges, although the magnitude of the effect was modest (34–36). There are some conceptual problems with this approach, however, as well as practical barriers to implementation. For inpatients, where there is no direct reimbursement for laboratory tests under the diagnosis-related group system, charges are largely irrelevant. In this setting, costs/expenses would potentially be useful, but many laboratories do not have rigorous cost information readily available. Moreover, the cost of performing many laboratory tests is small (often less than $5). Rather than display actual costs or charges, some EMRs display graphics (e.g., dollar signs) showing the relative cost of tests, but this has the obvious drawback of too small a scale, and providers are unlikely to know what the actual cost/charge is based on a graphic display. Being able to display costs/charges also relies on constant updating of the database, as these values change frequently.

Most EMR systems have laboratory modules with the capability to identify duplicate orders, to flag orders that meet specific criteria (e.g., the number of blood cultures ordered within a defined period), to document test changes or cancellations, and to notify providers of changes to an order. These capabilities allow laboratories to improve test utilization through simple algorithms. This is particularly important in settings where more than one provider may be ordering tests for patients, a circumstance that results in increased duplicate testing (37, 38). One author has helped to implement an intervention in his institution that blocks unnecessary (i.e., redundant) same-day repeat test orders. The tests on this list were vetted with the medical leadership prior to intervention, and means are available to complete these orders if the provider believes they are medically necessary. A clinical decision support tool (CDST) that blocked same-day duplicate orders was studied by one group for 2 years. That CDST blocked 11,790 unnecessary duplicate tests, saved an estimated $183,586 in materials and labor, and importantly was not associated with any untoward clinical outcomes (29). Although the cost avoidance associated with specimen collection and transportation was not calculated, it too was likely significant.

Contemporary EMRs also have the capability for CPOE that can be linked to information regarding other laboratory tests, drug allergies and other adverse drug reactions, nutritional data, radiographic images, and clinical findings. In general, these systems have the ability to integrate this information so that orders can be modified either by alerting the provider at the time of entry or by the CPOE system directly. More advanced CPOE systems have all of these features as well as the ability to incorporate practice guidelines, clinical pathways, and other efforts to improve care (39–41).

EMR-Based Feedback in Reports

Even without a rules-based CPOE system, many EMRs can be programmed to provide information about the cost of laboratory tests, information regarding clinical utility of tests, and warnings about the use of certain drugs in patients with specific laboratory findings (such as renal failure). Many EMRs have the ability to show specific comments either automatically (based on rules within the system) or by manual *ad hoc* request. These systems can be an inexpensive and effective way to disseminate information to providers.

There are a number of types of feedback that can be given to providers. In clinical microbiology, one of the most commonly used types of feedback is the selective reporting of antimicrobial susceptibility test results, with or without comments, to help guide interpretation of the results. Even without comments, the provider receives test results only for those antimicrobial agents that are likely to be clinically relevant, information that should improve patient care. Another common type of feedback is the average daily cost of drugs that are reported for antimicrobial susceptibility test results. Other common types of feedback for microbiology tests include comments regarding the presence of contaminating microbiota, the lack of clinical relevance for some types of testing (e.g., microorganisms recovered only from broth cultures), specimen adequacy (e.g., evaluation of sputum specimens for neutrophils and epithelial cells), the types and numbers of microorganisms recovered from midstream urine specimens and their likely clinical relevance, and the number and adequacy of specimens received for blood culture. Given adequate laboratory and computer resources, comments can be developed to help guide the interpretation of most laboratory tests.

Institution-Based Approaches to Control

As with laboratory-based approaches to control, a number of institution-based approaches to control laboratory test utilization have been described (Table 44.3). The two types of approaches are not exclusive: Each complements the other, and used together, they might be more effective than either type of approach used alone.

Working with Providers

One can approach providers in a number of ways when changes are needed. One effective strategy is to first meet with the provider leadership and senior physicians before

本书版权归John Wiley & Sons Inc.所有

Table 44.3 Institution-based approaches to control

Working with the medical staff
Formal protocols/patient care algorithms validated by medical staff
Working with the nursing staff
Institutional protocols
Using major problems to effect change

meeting with the general membership. This is because (i) medical staff leaders typically have a better understanding of issues that necessitate changes, (ii) leaders are selected because of their experience and the respect that other providers have for them, (iii) most leaders have been through a number of changes and thus are less resistant to new changes, and (iv) obtaining leader support facilitates changing the way medicine is practiced. Medical staff leaders can also serve as a liaison with the general membership.

In teaching hospitals and clinics, one of the leading roles of the medical staff is to provide adequate supervision of students and residents. Laboratory test overutilization is well known to be higher in teaching settings, is partially attributable to trainees (42), and requires adequate oversight. One of the more important roles of attending physicians is to teach and train when to order tests; which tests to order; how to interpret test results in the context of the patient's other clinical, laboratory, and radiographic findings; and what interventions (if any) should be based on the test results.

Formal Protocols Validated by Provider Leadership

A potentially effective means of implementing changes is the use of clinical protocols or guidelines that have been reviewed and validated by the provider leadership, which is often the organized medical staff. These have a number of synonyms, including care protocols, clinical pathways, key clinical pathways, clinical care standards, and patient care guidelines. When developed correctly, these protocols incorporate findings and guidelines from evidence-based medicine, as well as specific guidelines from professional societies and organizations such as the Centers for Disease Control and Prevention, into the practices and workflow of an organization. The end result should be the application of state-of-the-art medical knowledge to a specific patient population in a specific setting. However, in reality using these protocols and guidelines is not so straightforward, nor is their acceptance by providers always without controversy. One of the biggest obstacles to using protocols and guidelines is that there are frequently different ones put forth by a number of organizations, often with very different interpretations of the published evidence and as a result their recommendations. Implementing them in a clinical setting can require adaptation to local circumstances and different patient populations, neither of which may have been addressed in the recommendations. Providers can also be slow or even resistant to using them based on previous experience (clinical habit) and other factors (43). To address these challenges is not simple: education alone is likely to be ineffective. As discussed in the section on EMR-based approaches, the most effective and sustainable approach will be multifaceted and one where guidelines and recommendations are embedded in the test ordering process.

Healthcare in many settings is more team-based than it was in the past, with advanced practice providers (APPs, e.g., physician assistants and nurse practitioners) taking on roles previously limited to physicians. Much of inpatient care, both general and specialty, as well as primary care, is provided by APPs, and in all settings nurses and medical assistants provide much direct patient care. As a result, implementing changes intended to change test utilization requires involvement of multiple groups of providers, not just physicians. This means communicating with a broader group of providers and making certain that changes in EMRs are done in such a way so as to integrate the appropriate test ordering among these different roles.

The Concept of a Test Formulary

Pharmacies improve the use of drugs, reduce costs, and work to minimize or slow the emergence of antimicrobial drug resistance by several mechanisms, one of which is the use of drug formularies. At its most basic level, a formulary is simply a list of drugs that have been approved for use in a given healthcare setting. The concept of developing a similar mechanism to guide laboratory test utilization is not new; all laboratories select specific assays and specific platforms on which to run those assays rather than offering multiple tests for the same condition. This is part of good laboratory practice. What is a newer concept involves a more directed and systemic approach involving development of a tiered formulary that is linked to the health needs of the patient population as well as the drugs and other resources used for patient care within that system (44). A number of models exist, but all have in common a list of tests available to any provider at any time, a second tier of tests restricted to a specific group or groups of providers (usually specialists who can order certain tests relevant to their specialty), a third tier of tests available only under specific circumstances and with prior authorization, and a fourth tier of tests that are not available (44). The analogy with a drug formulary is only partly accurate, as laboratory tests are not used the same way as drugs, do not have the same direct impact on patients, and often are used for many different conditions; furthermore, there are far more laboratory tests than there are drugs. That said, there are enough similarities between the two that providers will be familiar with how they work and the rationale behind them.

本书版权归John Wiley & Sons Inc.所有

A test formulary can also specify subgroups of tests that are appropriate for use in the inpatient setting, outpatient setting, or both. In particular, use of tests that are performed only in reference laboratories are often less useful or appropriate for the inpatient setting. First, the results of many (if not most) tests sent to reference laboratories are not available prior to discharge and therefore are not clinically relevant in the inpatient setting. Second, because of the way reimbursement occurs (i.e., the diagnosis-related group system), hospitals do not receive reimbursement for many of these tests when they are ordered on an inpatient basis. In contrast, if one waits to order these tests in an outpatient setting, the healthcare system can receive reimbursement from the patient's insurance or healthcare plan. Last, it is often better to defer more esoteric testing to an outpatient specialty or primary clinic that is better suited for overall coordination of patient care.

Using Major Events to Effect Change

Major events in healthcare provide opportunities to make changes that otherwise may not be possible. This is neither a cynical observation nor opportunistic management. Rather, it is recognition of the fact that some issues cannot be dealt with under normal circumstances because of political, financial, or other constraints. During major events, however, these constraints may diminish or disappear, providing an opportunity to bypass them. Change occurs more easily during major events because there typically is an acknowledgment that the status quo no longer can be preserved, individuals may need to take a different view of circumstances, and many departments may be involved. A particularly opportune time to eliminate procedures or tests that are of marginal utility, or that providers are unwilling to give up at other times, may be during a reduction in operating budgets, changes in organizational management, changes in ownership, relocation of laboratory facilities within the building or complex, construction of new facilities, implementation of EMR systems (particularly when rules-based orders will be implemented), and changes in academic or other types of affiliations. Although these changes may not afford equal opportunity for change, or for the same types of change, laboratory directors should look for opportunities that accompany what otherwise are challenging circumstances.

Important allies for implementing changes include the organizational offices that oversee patient safety and quality as well as that for compliance. The former plays a number of important roles within organizations, including ensuring compliance with accreditation standards, investigating adverse events, performing root cause analyses, and developing organizational policies and procedures. In contrast, a compliance office deals primarily with business ethics, business practices, and compliance issues related to financial matters. The safety and quality office, given its broader role within the organization, can assist with change by helping develop clinical protocols, particularly those that involve changing organizational policies and procedures. It can also assist with change when an adverse event or the findings from a root cause analysis indicate that a change is necessary. Obviously, either office can assist with change when the change is necessary for compliance reasons. In some cases, this type of assistance can be invaluable for making changes that are contentious but necessary.

What Works and Doesn't Work: How To Take the First Steps

There is a substantial body of literature regarding the effectiveness of different methods for changing laboratory test utilization. Most of this literature reflects the notion that *changing* test utilization usually means *restricting* test utilization. This undoubtedly is an oversimplification of the issue, as there are good examples of how laboratory tests can be underutilized as well as overutilized. Nonetheless, the problem of overutilization receives more emphasis because it probably is more pervasive in modern medicine than is underutilization, and decreasing overutilization can yield substantial cost savings. It is true that increasing the use of tests that are underutilized can decrease costs in the healthcare system as a whole, but until recently, few systems have taken the broader approach to cost control, instead focusing cost control efforts on specific issues.

Changing/controlling laboratory test utilization means changing/controlling provider (usually physician) behavior. This has proven to be a complex and difficult issue for healthcare systems to address, as most interventions intended to change physician behavior have been ineffective or have had only a temporary effect (45, 46). As reviewed by Valenstein, physician education has been shown to be an ineffective approach to changing test utilization (despite being the most commonly used intervention), and both clinical and financial feedback have been shown to have variable effectiveness (46). In the same review, Valenstein noted that administrative interventions have been shown to be effective in changing test utilization (46). These include requiring justification for certain tests, changing the test request process, and changing "informal testing rituals" (46, 47). The first of these, requiring justification for certain tests, may be an effective intervention, but it is impractical to implement in many settings and almost certainly will be unpopular with physicians. The second, changing the test request process, may ultimately be the most practical and effective intervention, particularly when it involves the use of CPOE systems. Hindmarsh and Lyon report a similar observation (48). The third intervention, changing testing habits, usually falls under the penumbra of clinical

本书版权归John Wiley & Sons Inc.所有

pathways, and in settings where physicians adhere to the pathways it can be an effective intervention (49).

In their review, Axt-Adam et al. noted that one explanation for the lack of effectiveness of many interventions is that physician behavior depends upon the physician's personality, education, training, specialty, location of practice, years of clinical experience, estimated test charges, and expectations (45). Malcolm et al. also reported that "personal factors" affect the way physicians use laboratory tests (50). The effect of clinical experience on test utilization has been reported in a number of studies, one recent example being the increased use of ancillary tests by inexperienced physicians in the evaluation of acute febrile illness (51). In his review, Valenstein reported that risk-taking attitudes might affect test-ordering behavior, although some investigators have not found a relationship between personality and test utilization (46). Given the number of factors that may affect test-ordering behavior, it should come as no surprise that many specific interventions have been found to be ineffective in changing the test ordering behavior of providers. It may be that at any time and in any place only a subset of providers is amenable to a particular intervention and that over time no static intervention will result in sustained changes in test utilization behavior. As Valenstein noted in his review, "to the extent that differences in the test-ordering behavior of physicians reflect ingrained and immutable psychological traits, one would expect little success in modulating test utilization by trying to influence individual providers" (46). This may be the most realistic assessment of the effect of personality on test utilization behavior and the lack of effectiveness of educational interventions in changing that behavior.

Despite the reported variable success in changing test utilization behavior and the difficulty in sustaining changes, there is cause for optimism. First, there has been for many years little or no doubt among laboratorians—and many clinicians—that more laboratory tests are performed than are needed for patient care, and that many laboratory tests are used incorrectly (52, 53). Second, there is a growing awareness among providers that while healthcare resources are limited, the available resources should be allocated so as to maximize benefit to patients (25). Third, improvements in information systems have resulted in EMR systems that have the capability to affect test utilization via immediate feedback to providers as well as by use of artificial intelligence. Last, the growing body of literature on evidence-based medicine makes it much easier for healthcare systems to develop rational clinical pathways and for laboratorians to use those pathways as part of their strategy to change test utilization.

From a purely pragmatic standpoint of making changes in diagnostic microbiology testing, McLaughlin has published a step-by-step approach that is rational, practical, and (by anecdotal experience) effective (14).

Table 44.4 Implementation of diagnostic microbiology policies[a]

Base proposed changes on published data
Supplement these data with in-house data
Gain the support of the infectious diseases service
Discuss proposed changes in advance with influential providers
Educate providers who will be affected by the changes
Announce changes by effective means of communication
Educate laboratory staff who will implement the changes
Revise laboratory manuals accordingly
Initially give providers an "override" mechanism
Provide necessary explanations and follow-up to users

[a] Modified from reference (14).

Table 44.4 shows a modified version of this approach. As emphasized in McLaughlin's approach, building support for change is crucial (14). Many changes that are needed to make a laboratory more cost-effective or clinically relevant are contentious, even when they are not costly. There are several reasons for this. The first is that making changes can mean taking something away from providers, and it is axiomatic that it is more difficult to take something away than it is to not give it in the first place. The second reason is that making changes shifts control from the provider to the laboratory, and providers may perceive that this affects their clinical autonomy and/or their ability to act on behalf of their patients. Last, making changes is difficult under most circumstances, even when it is perceived to be in one's best interests. To facilitate changes, having the support of departmental and organizational leadership is crucial. By support, one hopes for an understanding and analysis of the recommended changes, including an understanding of the impact on services as well as of benefits, costs, and alternatives. In all circumstances, one should avoid presenting support as an edict, as this approach may yield not the desired response but instead its opposite.

Perhaps the single most effective argument that can be presented to providers is to emphasize that the change will result in the most effective care for their patients (25). That may mean that the change is supported by evidence-based medicine, published guidelines, or other sources of information that are based on rigorous analysis of published information. In the same way, providers are very good at following recommendations that result in standardized approaches to care, which is much easier now that EMRs provide the means to standardize order sets, publish helpful information during the test ordering process, and block unnecessary testing such as duplicate tests. In other words, rather than attempt to affect test ordering patterns by individual providers, a better approach is to create systems in which appropriate test ordering patterns become the standard, expected approach.

本书版权归John Wiley & Sons Inc.所有

Putting It All Together

Base Policy Approaches and EMR-Based Controls on Evidence-Based Medicine

The published data about changing physician behavior indicate that most approaches achieve only a temporary effect or are ineffective altogether. Of the described methods that have been shown to be effective, use of EMR-based controls may be one of the more effective methods. Data regarding the effectiveness of evidence-based medicine as a tool for limiting test utilization are available for only a limited number of tests, but the data that are available (as well as anecdotal experience) suggest that physicians may be more accepting of changes that are derived from evidence-based medicine (54). There are at least two reasons why this observation may be true. First, by the nature of their education and training, physicians are more receptive to information based on sound scientific or medical research. Second, information that is scientifically persuasive is likely to be adopted as the standard of care, and physicians by and large adhere to what is perceived to be the standard of care within their community. Thus, one approach to increase the likelihood that physicians will accept change is to use EMR-based controls on physician ordering and to base the changes on evidence-based medicine. As stated previously, one of the advantages to the use of EMR-based controls is that test-ordering patterns can be tracked automatically, thereby generating physician-specific utilization data.

Track Results

As with any type of decision to make changes within an organization, the effectiveness of changes in laboratory test utilization is determined by (i) the quality of the decision to make the change, (ii) the success of the implementation, (iii) the likelihood that the intervention can be sustained, (iv) the willingness to modify the change as needed, and (v) whether the change improves patient care and/or outcomes. Documenting the effectiveness of the change requires the collection of data prior to implementation of the change followed by tracking the results of the change. For some changes, this is simple. Changes made to decrease or increase utilization of a specific test can be tracked simply by auditing test utilization over specific intervals. On the other hand, changes intended to improve patient care or outcomes require the collection of large amounts of data, often over long periods of time, and interpretation of the data in light of other clinical, radiographic, and laboratory findings. In some instances, they require formal study of the issue via randomized clinical trials. Finally, feedback to the governing bodies (e.g., medical executive committee, board of governors) of the positive outcomes (e.g., improved response, decreased length of stay, or cost savings) is important, as it builds relationships and trust, which will be important for your next proposal.

The Plan, Do, Study, Act Model

Once the effects of a change have been tracked for some time, a decision can be made to either continue the change without modification, to modify it, or to discontinue the change. This approach parallels what The Joint Commission for many years promoted as the plan, do, study, act approach for making change. The approach is self-explanatory, is simple, and can be used to address many types of issues. For this approach to be used effectively, the study and act stages of the process require the use of quantifiable data that can be tracked through time. Nardella et al. described a model system that incorporates many of the issues discussed in this chapter (47). The model is a good example, without use of the specific terms of the plan, do, study, act model for creating an effective intervention.

The Future: Better Teaching and Training

Because physicians, and those working under their supervision, drive the demand for most laboratory testing, it would seem intuitive that medical education and training should place a priority on test ordering as part of learning to care for patients. Unfortunately, this is not the current state in the United States, either in undergraduate or graduate medical education (GME). In fact, past GME tradition has caused some of our current problems; omissions were chastised more often than commissions: "Did you order/get X?" and not "Why did you order/get X?" was the paradigm for generations of trainees. Cooke (55) clearly delineates the responsibility of GME to inculcate cost-consciousness, and Weinberger (56) presents a realistic mechanism for changing this paradigm, as he advocates for the addition of a seventh competency, cost-conscious care and stewardship of resources, to the six general competencies promulgated by the Accreditation Council for Graduate Medical Education (ACGME). The ACGME Pathology requirements mandate that a resident must perform a quality improvement project [Pathology Program requirement IV.B.1.d (1).(h)]; some of these projects have been in test utilization. Test utilization is also mentioned, albeit by way of example, in the Pathology Milestones (Systems Based Practice 3, Level 3), it is only by way of example (57). Phillips et al. suggest that practice habits concerning utilization, which were demonstrated to be long and enduring, were developed in training (58). This suggests that a greater influence during the "imprinting" phase of professional development could have an impact on future utilization. The best patient care and outcomes will derive from stewardship, which is what Weinberger's proposed seventh competency really is about, particularly if implementation of this competency changed care based on evidence. It is unlikely that many GME

本书版权归John Wiley & Sons Inc.所有

programs will implement (or even explicitly acknowledge) this competency in the evaluation of trainees unless required to do so.

SUMMARY

The principle that guides changes in laboratory test utilization must be that of clinical relevance. Clinically relevant tests may or may not be cost-effective, but tests that are not clinically relevant cannot be cost-effective, regardless of how inexpensive they may be. Although the tools for assessing clinical relevance are imperfect, efforts are being made to improve the way that clinical evaluations of laboratory tests are performed so that assessments of clinical relevance, the impact on patient outcomes, and cost effectiveness can be standardized and quantified. Until those assessment tools are available, however, laboratorians should make use of the characteristics of clinically relevant tests presented in Table 44.1.

There is now good evidence that any effective and sustainable approach must include a combination of interventions (59–61). Based on the available evidence, and on the experience of the authors and others, changing laboratory test utilization requires (i) careful planning and preparation; (ii) establishment of guidelines (clinical pathways or other types) derived from evidence-based medicine; (iii) a detailed plan for introducing and implementing the changes; (iv) use of informatics to disseminate guidelines, automatically perform some tasks (e.g., elimination of duplicate tests), and track data regarding utilization; (v) continuous monitoring of the effectiveness (and the effects of) the change; and (vi) continuous modifications as necessary (62).

KEY POINTS

- A number of laboratory-based approaches to controlling laboratory test utilization are described, including newsletters, policy changes, personal and *ad hoc* communication, EMR-based controls, and EMR-based feedback in reports.
- A number of institution-based approaches to controlling laboratory test utilization are described, including approaches to working with providers, using formal protocols that have been validated by the medical staff, institutional protocols such as clinical pathways, and major events (such as introducing a new EMR) to effect change.
- Effective control of laboratory test utilization requires the use of more than one approach or intervention; use of single approaches is less effective. Of the different types of interventions that have been evaluated, education appears to be the least effective.
- Use of an integrated EMR provides an opportunity to standardize test ordering, implement laboratory formularies, and provide immediate feedback to providers, approaches to controlling utilization that otherwise are not possible (or at the least not feasible).
- Effective interventions require the tracking of results, modification as indicated by data, and sustained effort. Without ongoing monitoring and effort, most interventions have only a transient impact.

GLOSSARY

College of American Pathologists (CAP) One of the professional societies for pathologists. One of the organizations that is deemed to accredit laboratories and that provides a program for proficiency testing. CAP also provides services such as Q-Probes and Q-Tracks (see below).

Computerized physician order entry (CPOE) system A computer-based system, or function within an integrated EMR, for placing clinical orders. Some systems have the ability to integrate orders with pharmacy and laboratory data.

Cost-benefit analysis "Cost-benefit analysis is a way to compare the costs and benefits of an intervention, where both are expressed in monetary units" (3).

Cost-effectiveness analysis "Cost-effectiveness analysis is a way to examine both the costs and health outcomes of one or more interventions. It compares an intervention to another intervention (or the status quo) by estimating how much it costs to gain a unit of a health outcome, like a life year gained or a death prevented" (3).

Electronic medical record (EMR) An electronic (digital) collection of medical information about a person that is stored on a computer. An EMR includes information about a patient's health history, such as diagnoses, medicines, tests, allergies, immunizations, and treatment plans. EMRs can be seen by all healthcare providers who are taking care of a patient and can be used by them to help make recommendations about the patient's care. Also called electronic health record (EHR).

Evidence-based medicine The application of medical data (evidence) that have been analyzed using rigorous criteria to clinical decision making.

Laboratory information system (LIS) A computer system, or a module within an integrated EMR, that is used to order laboratory tests and report test results. Most can be interfaced directly with instruments to facilitate test result reporting and to minimize the need for manual data entry.

Q-Probes A program provided by the CAP that allows laboratories to collect data regarding laboratory processes and to compare their data with data collected from peer organizations. The data are collected for one time only.

Q-Tracks A program provided by the CAP that allows laboratories to collect data *through time* regarding laboratory

本书版权归John Wiley & Sons Inc.所有

processes and to compare their data with data collected from peer organizations on a quarterly basis.

Quality assurance (QA) Systematic approaches to assessing and improving the quality of care within a specific healthcare setting (e.g., a hospital or clinic) or healthcare program.

The Joint Commission (TJC) An organization that accredits most hospitals and healthcare organizations in the United States. TJC can also accredit clinical laboratories as a deemed organization.

REFERENCES

1. **Plebani M, Panteghini M**. 2014. Promoting clinical and laboratory interaction by harmonization. *Clin Chim Acta* **432**:15–21.

2. **Wilson ML**. 1997. Clinically relevant, cost-effective clinical microbiology. Strategies to decrease unnecessary testing. *Am J Clin Pathol* **107**:154–167.

3. **Centers for Disease Control and Prevention. Office of the Associate Director for Policy and Strategy**. 2021. Economic evaluation overview. 3 March 2021. https://www.cdc.gov/policy/polaris/economics/index.html. Accessed 5 May 2022.

4. **Doern GV, Vautour R, Gaudet M, Levy B**. 1994. Clinical impact of rapid in vitro susceptibility testing and bacterial identification. *J Clin Microbiol* **32**:1757–1762.

5. **Russell LB, Gold MR, Siegel JE, Daniels N, Weinstein MC, Panel on Cost-Effectiveness in Health and Medicine**. 1996. The role of cost-effectiveness analysis in health and medicine. *JAMA* **276**:1172–1177.

6. **Wilson ML**. 2012. Malaria rapid diagnostic tests. *Clin Infect Dis* **54**:1637–1641.

7. **van Walraven C, Naylor CD**. 1998. Do we know what inappropriate laboratory utilization is? A systematic review of laboratory clinical audits. *JAMA* **280**:550–558.

8. **Lundberg GD**. 1998. The need for an outcomes research agenda for clinical laboratory testing. *JAMA* **280**:565–566.

9. **Aronson MD, Bor DH**. 1987. Diagnostic decision: blood cultures. *Ann Intern Med* **106**:246–253.

10. **Beekmann SE, Diekema DJ, Chapin KC, Doern GV**. 2003. Effects of rapid detection of bloodstream infections on length of hospitalization and hospital charges. *J Clin Microbiol* **41**:3119–3125.

11. **Zhi M, Ding EL, Theisen-Toupal J, Whelan J, Arnaout R**. 2013. The landscape of inappropriate laboratory testing: a 15-year meta-analysis. *PLoS One* **8**:e78962.

12. **Hauser RG, Shirts BH**. 2014. Do we now know what inappropriate laboratory utilization is? An expanded systematic review of laboratory clinical audits. *Am J Clin Pathol* **141**:774–783.

13. **Jones RN, Krisher K, Bird DS, College of American Pathologists Microbiology Resource Committee**. 2003. Results of the survey of the quality assurance for commercially prepared microbiology media. Update from the College of American Pathologists Microbiology Surveys Program (2001). *Arch Pathol Lab Med* **127**:661–665.

14. **McLaughlin J**. 1995. The implementation of cost-effective, clinically relevant diagnostic microbiology policies: the approach. *Clin Microbiol Newsl* **17**:70–71.

15. **Siegel DL, Edelstein PH, Nachamkin I**. 1990. Inappropriate testing for diarrheal diseases in the hospital. *JAMA* **263**:979–982.

16. **Fan K, Morris AJ, Reller LB**. 1993. Application of rejection criteria for stool cultures for bacterial enteric pathogens. *J Clin Microbiol* **31**:2233–2235.

17. **Morris AJ, Wilson ML, Reller LB**. 1992. Application of rejection criteria for stool ovum and parasite examinations. *J Clin Microbiol* **30**:3213–3216.

18. **Albright RE Jr, Christenson RH, Emlet JL, Graham CB III, Estevez EG, Wilson ML, Reller LB, Schneider KA**. 1991. Issues in cerebrospinal fluid management. CSF Venereal Disease Research Laboratory testing. *Am J Clin Pathol* **95**:397–401.

19. **Albright RE Jr, Graham CB III, Christenson RH, Schell WA, Bledsoe MC, Emlet JL, Mears TP, Reller LB, Schneider KA**. 1991. Issues in cerebrospinal fluid management. Acid-fast bacillus smear and culture. *Am J Clin Pathol* **95**:418–423.

20. **Tang YW, Hibbs JR, Tau KR, Qian Q, Skarhus HA, Smith TF, Persing DH**. 1999. Effective use of polymerase chain reaction for diagnosis of central nervous system infections. *Clin Infect Dis* **29**:803–806.

21. **Mein J, Lum G**. 1999. CSF bacterial antigen detection tests offer no advantage over Gram's stain in the diagnosis of bacterial meningitis. *Pathology* **31**:67–69.

22. **Perkins MD, Mirrett S, Reller LB**. 1995. Rapid bacterial antigen detection is not clinically useful. *J Clin Microbiol* **33**:1486–1491.

23. **Morris AJ, Wilson SJ, Marx CE, Wilson ML, Mirrett S, Reller LB**. 1995. Clinical impact of bacteria and fungi recovered only from broth cultures. *J Clin Microbiol* **33**:161–165.

24. **Morris AJ, Smith LK, Mirrett S, Reller LB**. 1996. Cost and time savings following introduction of rejection criteria for clinical specimens. *J Clin Microbiol* **34**:355–357.

25. **Rosenbaum L**. 2022. Peers, professionalism, and improvement—reframing the quality question. *N Engl J Med* **386**:1850–1854.

26. **Rubinstein M, Hirsch R, Bandyopadhyay K, Madison B, Taylor T, Ranne A, Linville M, Donaldson K, Lacbawan F, Cornish N**. 2018. Effectiveness of practices to support appropriate laboratory test utilization. *Am J Clin Pathol* **149**:197–221.

27. **Cadogan SL, Browne JP, Bradley CP, Cahill MR**. 2015. The effectiveness of interventions to improve laboratory requesting patterns among primary care physicians: a systematic review. *Implement Sci* **10**:167.

28. **Bindraban RS, Berg MJ, Naaktgeboren CA, Kramer MHH, Van Solinge WW, Nanayakkara PWB**. 2018. Reducing test utilization in hospital settings: a narrative review. *Ann Lab Med* **38**:402–412.

29. **Procop GW, Yerian LM, Wyllie R, Harrison AM, Kottke-Marchant K**. 2014. Duplicate laboratory test reduction using a clinical decision support tool. *Am J Clin Pathol* **141**:718–723.

30. **Procop GW, Keating C, Stagno P, Kottke-Marchant K, Partin M, Tuttle R, Wyllie R**. 2015. Reducing duplicate testing: a comparison of two clinical decision support tools. *Am J Clin Pathol* **143**:623–626.

31. **Lippi G, Brambilla M, Bonelli P, Aloe R, Balestrino A, Nardelli A, Ceda GP, Fabi M**. 2015. Effectiveness of a computerized alert system based on re-testing intervals for limiting the inappropriateness of laboratory test requests. *Clin Biochem* **48**:1174–1176.

本书版权归John Wiley & Sons Inc.所有

32. **Konger RL, Ndekwe P, Jones G, Schmidt RP, Trey M, Baty EJ, Wilhite D, Munshi IA, Sutter BM, Rao M, Bashir CM**. 2016. Reduction in unnecessary clinical laboratory testing through utilization management at a US Government Veterans Affairs hospital. *Am J Clin Pathol* **145**:355–364.

33. **Bates DW, Kuperman GJ, Jha A, Teich JM, Orav EJ, Ma'luf N, Onderdonk A, Pugatch R, Wybenga D, Winkelman J, Brennan TA, Komaroff AL, Tanasijevic MJ**. 1997. Does the computerized display of charges affect inpatient ancillary test utilization? *Arch Intern Med* **157**:2501–2508.

34. **Fang DZ, Sran G, Gessner D, Loftus PD, Folkins A, Christopher JY III, Shieh L**. 2014. Cost and turn-around time display decreases inpatient ordering of reference laboratory tests: a time series. *BMJ Qual Saf* **23**:994–1000.

35. **Feldman LS, Shihab HM, Thiemann D, Yeh H-C, Ardolino M, Mandell S, Brotman DJ**. 2013. Impact of providing fee data on laboratory test ordering: a controlled clinical trial. *JAMA Intern Med* **173**:903–908.

36. **Horn DM, Koplan KE, Senese MD, Orav EJ, Sequist TD**. 2014. The impact of cost displays on primary care physician laboratory test ordering. *J Gen Intern Med* **29**:708–714.

37. **Branger PJ, Van Oers RJM, Van der Wouden JC, van der Lei J**. 1995. Laboratory services utilization: a survey of repeat investigations in ambulatory care. *Neth J Med* **47**:208–213.

38. **Valenstein P, Leiken A, Lehmann C**. 1988. Test-ordering by multiple physicians increases unnecessary laboratory examinations. *Arch Pathol Lab Med* **112**:238–241.

39. **Peters M**. 1995. Managing test demand by clinicians: computer assisted guidelines. *J Clin Pathol* **48**:98–100.

40. **Peters M, Broughton PMG**. 1993. The role of expert systems in improving the test requesting patterns of clinicians. *Ann Clin Biochem* **30**:52–59.

41. **Smith BJ, McNeely MDD**. 1999. The influence of an expert system for test ordering and interpretation on laboratory investigations. *Clin Chem* **45**:1168–1175.

42. **Dine CJ, Bellini LM, Iwashyna TJ**. 2009. Team effect on variation in laboratory utilization on subspecialty services. *Acad Med* **84**(Suppl):S63–S66.

43. **Solomon DH, Hashimoto H, Daltroy L, Liang MH**. 1998. Techniques to improve physicians' use of diagnostic tests: a new conceptual framework. *JAMA* **280**:2020–2027.

44. **Malone B**. 2012. The future of lab utilization management: are lab formularies the answer? *Clin Lab News* **38**:1, 6–7

45. **Axt-Adam P, van der Wouden JC, van der Does E**. 1993. Influencing behavior of physicians ordering laboratory tests: a literature study. *Med Care* **31**:784–794.

46. **Valenstein P**. 1996. Managing physician use of laboratory tests. *Clin Lab Med* **16**:749–771.

47. **Nardella A, Farrell M, Pechet L, Snyder LM**. 1994. Continuous improvement, quality control, and cost containment in clinical laboratory testing. Enhancement of physicians' laboratory-ordering practices. *Arch Pathol Lab Med* **118**:965–968.

48. **Hindmarsh JT, Lyon AW**. 1996. Strategies to promote rational clinical chemistry test utilization. *Clin Biochem* **29**:291–299.

49. **Board N, Brennan N, Caplan G**. 2000. Use of pathology services in re-engineered clinical pathways. *J Qual Clin Pract* **20**:24–29.

50. **Malcolm L, Wright L, Seers M, Davies L, Guthrie J**. 2000. Laboratory expenditure in Pegasus Medical Group: a comparison of high and low users of laboratory tests with academics. *N Z Med J* **113**:79–81.

51. **Procop GW, Hartman JS, Sedor F**. 1997. Laboratory tests in evaluation of acute febrile illness in pediatric emergency room patients. *Am J Clin Pathol* **107**:114–121.

52. **Johnson HA**. 1991. Diminishing returns on the road to diagnostic certainty. *JAMA* **265**:2229–2231.

53. **Kassirer JP**. 1989. Our stubborn quest for diagnostic certainty. A cause of excessive testing. *N Engl J Med* **320**:1489–1491.

54. **van Wijk MA, van der Lei J, Mosseveld M, Bohnen AM, van Bemmel JH**. 2001. Assessment of decision support for blood test ordering in primary care. a randomized trial. *Ann Intern Med* **134**:274–281.

55. **Cooke M**. 2010. Cost consciousness in patient care—what is medical education's responsibility? *N Engl J Med* **362**:1253–1255.

56. **Weinberger SE**. 2011. Providing high-value, cost-conscious care: a critical seventh general competency for physicians. *Ann Intern Med* **155**:386–388.

57. **Accreditation Council for Graduate Medical Education**. 2019. Pathology Milestones. Second revision. https://www.acgme.org/globalassets/pdfs/milestones/pathologymilestones.pdf. Accessed 10 June 2022.

58. **Phillips RL Jr, Petterson SM, Bazemore AW, Wingrove P, Puffer JC**. 2017. The effects of training institution practice costs, quality, and other characteristics on future practice. *Ann Fam Med* **15**:140–148.

59. **van Walraven C, Goel V, Chan B**. 1998. Effect of population-based interventions on laboratory utilization: a time-series analysis. *JAMA* **280**:2028–2033.

60. **Plebani M, Zaninotto M, Faggian D**. 2014. Utilization management: a European perspective. *Clin Chim Acta* **427**:137–141.

61. **Fryer AA, Smellie WS**. 2013. Managing demand for laboratory tests: a laboratory toolkit. *J Clin Pathol* **66**:62–72.

62. **Erlingsdóttir H, Jóhannesson A, Ásgeirsdóttir TL**. 2015. Can physician laboratory-test requests be influenced by interventions? *Scand J Clin Lab Invest* **75**:18–26.

本书版权归John Wiley & Sons Inc.所有

XI

The Future of Clinical Laboratories

(SECTION EDITOR: **Timothy C. Allen**)

45 **The Future of Pathology and Laboratory Medicine: Political, Social, Economic, and Regulatory Impacts**
Lisa M. Stempak and Mark Rodgers

46 **The Future of the Clinical Scientist Workforce**
I. J. Frame, Donna Gaffney, and Jana Bagwell

47 **Electronic Health Records and Their Implications and Opportunities for Laboratories**
Roger L. Bertholf

48 **Current Trends in Instrumentation and Technology: A Look toward the Future**
Patrick B. Kyle and Lauren McVoy

49 **The Future Practice of Laboratory Medicine**
Christopher Zahner and Peter McCaffrey

本书版权归John Wiley & Sons Inc.所有

本书版权归John Wiley & Sons Inc.所有

45

Introduction
The Current Environment of Healthcare
Current Regulations
CLIA '88 • HIPAA • OSHA Standards for Occupational Exposure to Blood-Borne Pathogens • Physician Self-Referral Law (Stark Law)
Liability Considerations
Bioterrorism and Emerging Highly Infectious Diseases
Recent History • Future Impact
Long-Term Effects: Legislation, Regulation, and Accreditation
Quality, Value, and Patient Safety • Financial Considerations of the Patient Safety Movement • The "No Surprises" Act
Issues Affecting Academic Laboratories and Research
Financial, Regulatory, and Staffing Concerns • Biorepositories, Restrictions on Use of Human Tissues, and Stem Cell Research
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES
APPENDIX

The Future of Pathology and Laboratory Medicine: Political, Social, Economic, and Regulatory Impacts

Lisa M. Stempak and Mark Rodgers

OBJECTIVES

To detail the major features of the current healthcare environment

To describe current regulations that govern laboratory medicine

To identify how political, social, and economic events will influence the practice of pathology and laboratory medicine in the future

All predictions are wrong, that's one of the few certainties granted to mankind. But, though predictions may be wrong, they are right about the people who voice them, not about their future but about their experience of the present moment.

M. Kundera (1)

William Osler described medicine as "a science of uncertainty and an art of probability (2)." The uncertainty Osler ascribed to medicine can also be applied to the future of laboratory medicine, because political, social, and economic influences are acting on medicine in complex ways. Scientific and technological advances that have increased options and improved outcomes for patients have also increased costs and raised questions of how much and what kinds of medical care our societies are willing to support. The controversies surrounding the directions medical care will take complicate efforts to make predictions about the future of laboratory medicine. This chapter examines the current environment of laboratory medicine in relation to political, social, economic, and regulatory facets and attempts to identify healthcare trends that may influence its future. Regulatory requirements are reviewed superficially to illustrate some of the challenges. More detailed and current information on these topics can be located in the references and cited resources.

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch45.

The Current Environment of Healthcare

Healthcare in the United States has seen rapid advances in the quality and effectiveness of care, with arguably less consistent improvements in access to

本书版权归John Wiley & Sons Inc.所有

that care. Because costs of care have increased in conjunction with the scientific and technical advances in medicine, questions of what care should be available and how the resources for that care should be distributed are continually being raised. The economic future of healthcare relies heavily on the following identifiable trends and concerns.

- The current healthcare delivery system is often viewed as having problems with access to care and the overall quality and safety of care that is provided.
- Patient demographics and technological advances in diagnosis and therapy are driving major increases in healthcare costs, though increasing expenditures in healthcare do not necessarily produce proportionate increases in life expectancy (3).
- Molecular technologies and "personalized medicine," because of their novelty, raise new questions of how to appropriately regulate their development and use.
- Systems for healthcare funding are often perceived as dysfunctional by consumers, healthcare providers, and those who ultimately pay for healthcare and health insurance.
- Conditions in healthcare markets encourage shifting of costs between patients, physicians, insurers, providers of healthcare-associated materials and services, and those who fund healthcare service. These conditions also encourage adversarial relations, sometimes in preference to cooperation between interested parties. Although significant modification of the managed-care system continues to occur, there is a notable absence of any consensus about the contours of politically or economically viable options.
- Concerns exist about the financial sustainability of Medicare and Medicaid, with associated debates about the role of state and federal government funding in healthcare and other social safety net programs.
- The Affordable Care Act makes extensive modifications to healthcare financing and delivery, to a greater extent than any other legislation since the creation of the Medicare and Medicaid programs. While there have been queries about the constitutionality of the Affordable Care Act, the major provisions and the core of the entire law were affirmed by the Supreme Court three times, most recently in June 2021 in the case of *California v. Texas* (4).

Current Regulations

In the United States, government intervention to promote health, safety, and welfare has traditionally been the province of state and local governments. Regulatory intervention in healthcare was minimal until the 20th century. Significant federal involvement in healthcare began with the Social Security Amendments of 1965, which provided for development of the Medicare and Medicaid programs (5). Historically, regulations concerning healthcare, public health, and laboratory medicine specifically have tended to reflect social and political concerns. Trends in laboratory regulations are influenced by the competing interests of patient health and safety versus the societal disinclination to regulate and restrict commerce. Legislative and regulatory initiatives to establish and regulate public health and safe laboratory testing practices in the mid-20th century were largely at the level of municipal and state health departments and were focused primarily on environmental issues such as safe water and food, sanitation, and infectious-disease prevention. In the later part of the 20th century, Congress enacted legislation enabling regulations with continuing extensive impact on laboratory medicine. The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are two of the main congressional actions of 20th-century federal laws and regulations that are particularly pertinent to pathology and laboratory medicine services. The Occupational Safety and Health Administration (OSHA) standards for occupational exposure to blood-borne pathogens and the Physician Self-Referral Law, commonly known as the Stark Law, which prohibits self-referral by healthcare providers, have also had considerable impact on the practice of pathology and laboratory medicine.

CLIA '88

CLIA '88 represents the foundation of regulation and accreditation of laboratory testing in the United States (6). Preceding CLIA '88, the Clinical Laboratory Improvement Act of 1967 (CLIA '67) was the first federal law to regulate laboratory medicine (7). The impact of CLIA '67 was limited to laboratories engaged in interstate commerce or providing services to Medicare and Medicaid patients. The law provided for establishment of regulations for licensing of clinical laboratories, including personnel standards. Congress enacted CLIA '88 to protect patients against poor-quality laboratory testing, particularly in physician office laboratories and "Pap mills" in which cytotechnologists were paid for each cytologic Papanicolaou smear they interpreted for cervical cancer screening with no limits on the number of slides they could review during a work shift. The latter led to the creation of a cut-rate industry where lab employees were overworked, often performing more work than recommended to maintain diagnostic accuracy, undersupervised, and penalized if they resisted pressure to screen more slides or take additional cases home to read. Following a series of Pulitzer Prize-winning newspaper articles in the *Wall Street Journal* in 1988 that detailed these major flaws and

本书版权归John Wiley & Sons Inc.所有

exposed questionable laboratory testing practices, a series of congressional hearings resulted in the very rapid passage of the CLIA '88 amendments. Although the law was enacted in 1988, the regulations were not implemented until 1992, in part because of a prolonged and contentious rule-making process involving two federal agencies, the Health Care Financing Administration, now called the Centers for Medicare and Medicaid Services (CMS), and the Centers for Disease Control and Prevention (CDC). An extended public comment period and lobbying efforts by organized medicine and the laboratory equipment manufacturing industry as well as by groups representing hospitals attempted to make the regulations less stringent. At the same time, organizations representing laboratory professionals argued to maintain existing personnel and quality control standards. Although changes to the regulations continue to be made, the amendments in their current form have been well established for many years and are applicable to all testing performed on humans, with few exceptions and without regard to the venue of testing (site neutrality). The regulations encompass personnel standards, patient test management, quality assurance, proficiency testing, provisions for inspection and certification, and civil and criminal penalties for noncompliance. Laboratories have several inspection and accreditation options that include government and private sector organizations such as the College of American Pathologists (CAP) and The Joint Commission.

The future regulatory climate under CLIA '88. While initially viewed by some as regulatory overreach, CLIA is now widely accepted. It is unlikely that there will be serious legislative initiatives to significantly modify CLIA in the future. The broad outlines of laboratory practice under CLIA will continue to include the following key features for the foreseeable future.

Complexity categories. Complexity categories are ratings given to commercially marketed diagnostic tests by the U.S. Food and Drug Administration (FDA) based on their risk to public health. Depending on the complexity level of testing, there are different education and licensure requirements for laboratory personnel. The complexity categories are (i) waived testing, which encompasses simple laboratory tests with minimal regulatory requirements; (ii) provider-performed microscopy, encompassing a limited number of procedures (e.g., wet prep, KOH prep, fern test) commonly performed by nonlaboratory staff in physician offices in conjunction with patient visits; (iii) moderate-complexity testing, which consists of the bulk of routine chemistry and hematology tests; and (iv) high-complexity testing, which includes tests performed by anatomic pathology, cytopathology, blood banking, microbiology, cytogenetics, and histocompatibility sections and any test that is modified from the manufacturer's instructions or is a laboratory-developed test (LDT).

Waived testing. In the time since CLIA was implemented, the waived testing category has undergone the most change, with expansion of the original list of eight waived tests to the current number in excess of 1,400 test systems. Although many of these tests represent alternative analytic versions of common tests such as hemoglobin, occult blood, and urine dipstick testing, more specialized tests have been approved over time (e.g., respiratory virus testing and coagulation tests). There will be continuing efforts at the regulatory level to increase the scope and breadth of waived testing and continuing debate about the relative allocation of the responsibility for guaranteeing quality testing standards between the laboratories and the manufacturers of these diagnostic systems.

Personnel standards and quality control standards. Personnel qualifications, quality control standards, and inspection requirements vary with the complexity of testing. Some modifications in quality control requirements reflect changes in technology, particularly the advent of unitized, self-contained testing platforms. Recent changes have included the promulgation of a single set of quality control standards for all nonwaived testing (moderate and high complexity) as well as an option for reduction in frequency requirements with the implementation of individualized quality control plans (IQCP) for most areas of testing, with the exception of anatomic pathology and cytopathology (8).

Changes to CLIA and alternative approaches. Other changes to CLIA that have occurred over time include modification to the requirements for frequency of quality control performance, an increased regulatory focus on personnel qualifications and competency which includes six elements of assessment for each test system, and increasing emphasis on the responsibilities and involvement of the laboratory director in laboratory operations and ensuring the quality of testing (9). CMS has revised the guidelines to include risk management principles similar to those used in manufacturing industries.

A general consensus exists that the major components of CLIA pertaining to the complexity model, personnel requirements, patient test management, quality control, and proficiency testing will not change substantially. Change could occur through legislative action, but incremental change through regulatory action is more likely and would be far less likely to result in disruptive impacts on laboratory practice. Because of the rapid momentum of advances in complex molecular diagnostic technologies and in particular how it affects genomic medicine, the clinical, societal, and privacy implications of these

本书版权归John Wiley & Sons Inc.所有

modalities will likely invite continued regulatory attention (10, 11).

It is apparent that the debate over the degree of FDA oversight for LDTs will continue to be a focus of regulatory concern in the future. This topic gained national attention at the beginning of the coronavirus disease 2019 (COVID-19) pandemic when the FDA required laboratories to obtain emergency use authorization (EUA) prior to performing molecular LDTs to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which delayed much-needed widespread testing during a global health emergency. The FDA argument for greater regulatory oversight of LDTs stems from the assertion that while CLIA guidelines address the analytical validity of a test, there are no requirements for clinical validity. The FDA published its concerns in a 2015 paper that detailed 20 examples of LDTs that caused or may have caused actual harm to patients when there was not compliance with the FDA requirements (12). In 2021, the Verifying Accurate Leading-edge IVCT Development (VALID) Act was reintroduced to Congress, which proposes a premarket review by the FDA based on the degree of risk posed by the LDT.

HIPAA

Congress enacted the Health Insurance Portability and Accountability Act (HIPAA) partially in response to public concerns about portability of employer-provided health insurance for workers changing jobs as well as related concerns about denial of insurance coverage for preexisting medical conditions. Technical standards for electronic health information and significant new protections of patient privacy and information are also included in the law. HIPAA is considered by many as one of the most significant legislative and regulatory events impacting healthcare in the first decade of the 21st century. The HIPAA Privacy Rule established a set of national standards for the protection of certain protected health information (PHI) to ensure patient privacy and the security of electronic transactions. The privacy standards do the following:

- Limit the use and disclosure of PHI, restricting disclosures to "minimum necessary" purposes
- Provide patients the right to access their medical records, to know who has accessed their records, and to request amendments to their records and restrict access to their records for research purposes
- Establish criminal and civil penalties for improper use and disclosure

The regulations permit the use and disclosure of PHI for treatment, payment, and healthcare operations (e.g., quality assurance and competency activities, medical review, specified insurance functions, and business planning and management) without consent or authorization and allow for disclosure of PHI for treatment by another healthcare provider. More complete information can be found at https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html (accessed 14 May 2022).

Laboratory requirements. To comply with the regulations, a clinical laboratory is required to do the following:

- Designate a "privacy official" who is responsible for developing and implementing privacy rules and procedures
- Develop specific policies and procedures stating how PHI may be used and disclosed by its employees and agents in order to comply with the HIPAA rules
- Prepare a notice of privacy practices explaining how the laboratory will use, disclose, and protect PHI. While patient-facing physicians must routinely obtain written acknowledgment from the patient on the provision of the notice of privacy, pathologists and laboratories, as indirect care providers, are exempt from this requirement.
- Establish administrative, technical, and physical and electronic safeguards for PHI. These may include periodic audits, password protection schemes, and physical safeguards such as privacy filters on computers in high-traffic areas and secured backup copies of patient data.
- Train all personnel on understanding and enforcing privacy policies and procedures; training must be documented

The impact of HIPAA. The final privacy rule regulations specified that, by April 14, 2003, laboratories that transmit data electronically must implement policies and procedures safeguarding against unauthorized use of or disclosure of identifiable patient information. Subsequently, additional laws, such as the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, encouraged the utilization of a certified electronic health record (EHR) to improve quality, safety, care coordination, and greater ease for patients to access their records while strengthening the enforcement of civil and criminal penalties if HIPAA rules are violated. The Medicare and Medicaid Electronic Health Record Incentive Plan, also referred to as "meaningful use," gives financial incentives to providers who meet targets for objectives intended to promote improvement in patient care.

The future of HIPAA. HIPAA has had enormous operational and economic impacts upon the entire healthcare industry. Responses to the regulations have required significant resources and will continue to do so. The societal benefits of HIPAA in safeguarding patient privacy are

本书版权归John Wiley & Sons Inc.所有

considerable; however, the implementation and maintenance of these regulations pose logistical and financial challenges for an already heavily burdened healthcare system.

OSHA Standards for Occupational Exposure to Blood-Borne Pathogens

As part of its mission to establish standards for safe working conditions, OSHA developed standards for protection from blood-borne pathogens in 1991. The goal of these standards is to protect employees with regular and predictable occupational exposure to human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other blood-borne pathogens. With proper training and work practices, personal protective equipment, HBV vaccination, and medical surveillance and treatment postexposure, the risk of occupational exposure can be significantly reduced or eliminated. More complete information can be found at https://www.osha.gov/bloodborne-pathogens (accessed 14 May 2022).

Physician Self-Referral Law (Stark Law)

The Physician Self-Referral Law constitutes a series of congressional actions enacted sequentially over a period of several years that significantly limit the referral of a wide variety of services—including clinical laboratory testing—to entities in which the referring physician or immediate family member has a financial stake (13). The regulations are named for Rep. Fortney "Pete" Stark (D–CA), who was the legislative sponsor of the initial regulations enacted in 1992 (Stark I). Among the limitations imposed by Stark I was a general prohibition of a physician from making Medicare referrals for clinical laboratory services if the physician or an immediate family member had any financial interest in the laboratory receiving the referred work. The Stark II legislation, enacted in 1993, extended the regulations to Medicaid and broadened coverage to 10 additional designated health services, including physical and occupational therapy, radiology and imaging services, radiation therapy, and durable medical equipment, among other supplies and services. Enforcement is closely linked to other "fraud and abuse" enforcements of federal anti-kickback and "false claims" statutes (14). An area of concern to pathologists as well as hospital and independent laboratories has been the in-office ancillary services exemption under the Stark laws, which allows specialty physician groups (e.g., urologists, dermatologists, gastroenterologists) to "in-source" pathology professional and technical services into their office practices. The services are provided by affiliated or contracted pathologists and laboratory entities, with a portion of the revenue diverted to the clinical practice. The exemption is supported by physician groups who contend that provision of service in the office facilitates continuity and immediacy of patient care. However, a study from Georgetown University demonstrated that self-referring urologists billed Medicare for approximately 72% more biopsies and detected cancer at lower rates than urologists who derived no financial benefit from the pathology and laboratory testing, suggesting that self-referral leads to increased use and higher costs (15).

Liability Considerations

Full discussion of the impact of medical malpractice liability on pathology and laboratory practice is beyond the scope of this chapter, but it is worth noting that trends in medical malpractice litigation and reforms targeted at limiting malpractice liability have significant influence on pathology and laboratory medicine. Concerns about potential liability influence clinicians and pathologists to utilize more resources in excluding potential but remote diagnostic possibilities, sometimes called "defensive medicine." Other impacts include hesitancy to report results from methods not approved by the FDA or decisions by blood transfusion services to implement available screening tests for infectious diseases in the absence of evidence of clear benefit or regulatory requirements. Although these practices are not violations of existing laws or regulations, concerns about possible future civil law claims of failure to follow the perceived standard of care may lead to the implementation of more robust practices than necessary.

Bioterrorism and Emerging Highly Infectious Diseases

Recent History

In the wake of the events of September 11, 2001, credible threats of terrorism that included the potential for use of nuclear, chemical, and biological agents have had significant impacts on the funding and cost of providing laboratory services. The identification of clinical cases and environmental contamination attributable to deliberate dissemination of *Bacillus anthracis* through the mail system during the early part of 2002 directly affected microbiology laboratories and renewed focus on how to safely identify potential agents of bioterrorism in both clinical and public health laboratories. In addition to the terroristic uses of infectious agents, the concurrent occurrence of other natural emerging highly infectious diseases, such as Ebola, influenza caused by variant influenza viruses, severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and the ongoing COVID-19 global pandemic, have not only significantly impacted the public, the medical and microbiological community, and the state and federal government but also focused attention on technical capabilities, biologic safety infrastructure,

本书版权归John Wiley & Sons Inc.所有

and staff preparation. Implications of the COVID-19 pandemic will appreciably influence the role of public health and preparedness activities for emerging infections worldwide for years to come.

Future Impact

The potential for utilization of biologic agents for terroristic purposes and emerging highly infectious diseases continue to be a threat. Public concern and governmental action in response to these threats may have significant budgetary impacts on a wide variety of healthcare facilities, including laboratories. These budget impacts will include training costs, acquisition and deployment of equipment, facility modification, and other mandates, such as the CDC's 2003 implementation of the Federal Select Agent Program (FSAP), requiring laboratories to register with the government and report if they are in possession of certain biologic materials, designated "select agents," ensure their proper use and storage, and notify the FSAP if they are transferred. Additional information is available on the CDC website at https://www.selectagents.gov/index.htm (accessed 14 May 2022).

Increased federal concerns about laboratory preparedness may generate some increased funding for specific areas of laboratory medicine; however, it is more likely that in the event of actual or suspected biological attacks or emerging epidemics or pandemics, the impact on all areas of the clinical laboratory will be to significantly increase the scale of laboratory services, not only to detect the infectious disease but also because of potentially massive increases in demand for routine laboratory services required for the care of large numbers of acutely ill patients for potentially prolonged periods of time.

Long-Term Effects: Legislation, Regulation, and Accreditation

Legislative and regulatory laws and rules are the basis for much of the requirements for accrediting and certifying organizations. These requirements significantly affect delivery of and access to healthcare services. Increases in the fixed "overhead" costs of regulations tend to be more easily absorbed by larger entities, particularly in an industry in which prices and payments are often fixed by regulatory authorities or subject to market force constraints. Thus, additional regulatory mandates can be expected to continue to accelerate the trend toward the consolidation of laboratory services to larger entities. The trend of merging laboratory services is related to the broad movement of the consolidation of once-independent hospitals to larger hospital systems in response to economic considerations and other challenges facing the healthcare system driven by new legislation and changes in regulations.

Quality, Value, and Patient Safety

Published in 1999, the landmark report on the quality of healthcare in America from the Institute of Medicine (IOM), *To Err Is Human: Building a Safer Health Care System* (16), has had a transformative impact on the agenda of medicine and healthcare and, therefore, on the practice of pathology and laboratory medicine. The assertion that almost 100,000 patients die annually because of medical error has driven initiatives to improve the quality of care and to minimize risk to patients. More recent studies assert that 400,000 hospitalized patients experience some type of preventable harm each year and that the resulting medical errors add an additional $20 billion to healthcare costs annually, further highlighting the criticality of this problem (17, 18). Many educational, administrative, and regulatory changes intended to improve patient safety both at the national level and at the level of individual hospitals and caregivers have been implemented in recent decades. To achieve these goals, many healthcare systems have implemented standardized patient care algorithms and order sets for a variety of conditions that are designed to provide consistency in care and to ensure that necessary diagnostic testing and therapies are performed in order to optimize patient outcomes while reducing expenditures. Some argue that the numbers cited in the IOM report may be excessive, while others contend that they underestimate the gravity of the problem (19). Most agree, however, that efforts to improve safety have met with variable degrees of success, with the consensus that the IOM's ambitious goal of cutting deaths from healthcare error in half has not been met (20, 21). The impetus to embed value, quality, and patient safety into daily healthcare delivery will continue and is increasingly being linked to efforts to make healthcare more efficient and less costly. Hospital and physician performance metrics are available from both private and governmental sources such as Leapfrog Hospital Safety Group and the National Healthcare Safety Network (22), which were introduced as voluntary efforts to spur improvement and to provide patients and payors with data concerning performance. However, the use of such data to provide both incentives and penalties through payment and public disclosure has started with a focus on readmission rates and hospital-acquired conditions (23).

Financial Considerations of the Patient Safety Movement

The societal, market-driven, and political pressures for increased standardization in healthcare have led to a variety of initiatives to monitor and improve patient safety by many powerful private-sector and government entities. Many of these entities serve as a source of comparative data, performance-based ratings, and benchmarks. The impact of these initiatives has become apparent, and

本书版权归John Wiley & Sons Inc.所有

the requirement for external standards will continue to be prevalent in all areas of medical and laboratory practice—scientific, operational, fiscal, and legal. The interactions between the above-described initiatives for standardization, patient safety, and error prevention in conjunction with evidence-based medicine will be substantial and imperative for success in these various areas as well. It is evident that the prevention of adverse events caused by error has been confounded with other aspects of provision of optimal care (24). It may be reasonable to predict that standardization of laboratory practice will progress as a result of multiple factors, such as consolidation of laboratories and laboratory testing platforms, further advances in automation, bar-coding technologies, and other "fail-safe" patient and specimen identification mechanisms, including standardized nomenclatures and languages (25), and have positive impacts on patient safety outcomes. The availability of standardized nomenclatures and languages that will allow for coded capture, aggregation, and retrieval of granular (detailed) data expressed in a variety of terminologies and across a variety of information systems will become increasingly important in patient safety and quality improvement efforts as well as for routine operational applications. The efforts of public- and private-sector organizations to promote increased standardization and improvement in educational practices will also continue to play a positive role (26).

Several recent trends, including growth in point-of-care testing, increasing autonomy of advanced practice providers, and increasingly well-informed patients with a consumer mindset, will generate requests from patients for increased involvement and control of their medical care. In 2014, amendments were made to CLIA and the HIPAA Privacy Rule allowing patients to directly obtain their laboratory results from CLIA-certified laboratories within 30 days of request, whereas previously, only authorized persons such as the ordering or treating physician had access to the patient's test results. The final rule for this mandate contained an analysis of the operational and financial impact this change would have on laboratories and found that compliance would cost laboratories an aggregate of $59 million a year for the first 5 years, which could potentially be offset by allowing a fee for providing patients access to their health information. In early 2021, the Office for National Coordinator for Health IT's information blocking rule went into effect, which stated that healthcare entities, including laboratories reporting pathology and clinical test results, can no longer delay the release of health information to patients. While this allows patients access to their medical results in real time, there is concern throughout the medical community about patients potentially viewing results before their physician and the risk of unnecessary alarm if results are not interpreted in the correct clinical context (27).

The continuing push to improve quality and patient safety coupled with cost control mechanisms will increasingly limit payment to laboratories and pathologists. Medicare's Physician Quality Reporting System (PQRS) has been in place since 2006 as a form of pay-for-performance incentive. This is a generic approach to payment for hospital and professional services that provides additional incentives or payments for demonstrated performance of certain indicators. Penalties for physicians who did not submit qualifying data began in 2010, with annual increases thereafter. Currently, the Merit-based Incentive Payment System (MIPS) lists six clinical quality measures for pathology: reporting templates for Barrett's esophagus, radical prostatectomy, lung cancer (biopsy/cytology and resection specimens), and melanoma and biopsy reporting time for skin cancer. There are nine additional pathology-specific measures that were developed by CAP and approved by CMS that include quality measures such as turnaround times for biopsies, biomarker testing, and immunohistochemistry reporting, with a focus on diagnoses of malignancies.

The "No Surprises" Act

The "No Surprises" Act, which was legislated within the Consolidated Appropriations Act of 2021 and brought into effect in January 2022, includes directives to protect healthcare consumers from large, unexpected bills from out-of-network healthcare providers. Pathologists are affected by the Act when they are providing services outside an insured individual's insurance network. This is likely to be of more concern to pathologists in practices independent of larger healthcare organizations and those who are consultants to other pathologists who bill patients directly. The goals of the Act have received broad support from professional organizations, including CAP, but litigation around the independent dispute resolution process incorporated in the Act alleges that the process favors insurers over providers.

Issues Affecting Academic Laboratories and Research

The future of academic laboratories—one of the main sources of innovation and new knowledge that has infused clinical diagnostics—is unclear in light of several challenges and is linked to the overall health of academic medical centers (28, 29). This uncertainty reflects many realities, including the fiscal threats facing academic medical centers as they attempt to fulfill their traditional missions of patient care, education, and research in the face of decreasing clinical revenues, level or diminishing support for teaching activities, and heightened competition for research funding, as National Institutes of Health (NIH) funding support has either diminished or exhibited only slight increases over the past 20 years (30).

本书版权归John Wiley & Sons Inc.所有

Financial, Regulatory, and Staffing Concerns

Current issues facing academic laboratories include the following:

- Payment reductions to the Clinical Laboratory Fee Schedule (CLFS) as required by the Protecting Access to Medicare Act (PAMA) are set to go into effect in upcoming years, and Medicare reimbursement for common laboratory tests such as complete blood count, metabolic and lipid panels, and hemoglobin A1c will be reduced. Healthcare and professional organizations successfully petitioned Congress to delay these cuts until 2023, as it would add to the negative impact experienced by financially taxed laboratories in light of significant supply and labor costs in response to the COVID-19 pandemic. While reductions in Medicare reimbursement for clinical diagnostic tests were limited to 10% per year in 2018 to 2020, the proposed reduction cap will increase to 15% per year in 2023 to 2025.
- The debate over the degree of regulatory oversight that is appropriate for the use of LDTs for clinical diagnostic purposes will continue. Similarly, as the field of "personalized medicine" and targeted therapies evolves, there is increasing interest in monitoring laboratory diagnostics that include both a technical portion and pathologist diagnostic interpretation, which seemingly blurs the line between test performance and the practice of medicine. As targeted drug therapies for various malignancies depend on following specific staining protocols in the laboratory and accurate immunohistochemical assessment by the pathologist, there has been a recent focus by some accrediting agencies on monitoring proficiency testing for laboratories that perform this category of testing.
- While the shortage of qualified medical laboratory personnel has been recognized for some time, these concerns became amplified as a result of the COVID-19 pandemic. An aging workforce, a decrease in accredited training programs, and high rates of staff turnover have led to substantial vacancy rates across the country, resulting in significant quality and safety concerns (31). Successfully addressing this issue will be imperative for the long-term sustainability of laboratory medicine.

Biorepositories, Restrictions on Use of Human Tissues, and Stem Cell Research

Recent issues encountered in the research setting include the following:

- In conjunction with the expansion of molecular genetic testing and precision medicine, the establishment of robust, validated biorepositories to house specimens for specific disease states has become imperative, and development of these services has increased substantially in recent years. The need to ensure specimen provenance and preanalytic considerations, such as proper labeling, handling, and storage, has led to the establishment of biorepository accreditation programs. In 2019, CMS determined that CAP's biorepository checklist requirements met CLIA regulations. CAP's program aims to provide best practices to meet the legal and ethical framework when biospecimens are used in internal review board (IRB)-approved research (see https://www.cap.org/laboratory-improvement/accreditation/biorepository-accreditation-program [accessed 14 May 2022]).
- Restrictive patents and excessive restraints on the use of clinical specimens are two areas of concern to the research and laboratory community. Many professional and public organizations argue that such patents would impede scientific progress, lead to high laboratory testing costs, and delay necessary testing for patients, while interested corporations, industry groups, and portions of the academic research community contend that eliminating genetic patenting will impede research. In 2013, the Supreme Court ruled that human genes could not be patented, as they are a product of nature that allows laboratories to develop modifications of genetic tests previously restricted by patents. However, as recently as 2019, opponents have proposed a bill to lift the patent ban, citing the need to have a predictable path to protect new inventions.
- Stem cell research and its application to clinical therapeutics, tissue and organ transplantation, and reproductive technology constitute an area that is continually impacted by complex and interrelated legislative, regulatory, and administrative events. Issues with stem cell research as it relates to the use of human fetal tissues and genetic manipulation have long elicited strong and conflicting opinions from various constituencies, including the research and medical community, religious groups, and organizations committed to the research and treatment of specific diseases. The threat of funding uncertainties and federal and state restrictions on stem cell technologies may impede research in this area and force investigators to explore opportunities in countries that are more supportive of stem cell research.

SUMMARY

Political, social, and economic trends and events are inextricably intertwined and often interact with the legislative and regulatory arena in unpredictable ways. The future of healthcare funding in the United States remains uncertain and subject to continuing competition for resources within and outside the healthcare industry. As healthcare costs in the United States continue to rise and significantly exceed costs

本书版权归John Wiley & Sons Inc.所有

in other developed economies, it is predictable that legislative and regulatory directives as well as market forces will constrain that rate of growth and impose significant reductions on available resources for all areas of healthcare, including pathology and laboratory medicine. It is also predictable that the allocation of resources will increasingly take into consideration the value and effectiveness of services that are delivered. This will shift practice toward a medical effectiveness strategy that is determined by the gathering of patient data (testing), available therapeutic and management options, and positive outcomes (clinical relevance).

As economic pressures to reduce healthcare costs increase, laboratories will be required to reduce operating expenses. This may produce greater reliance on automation, consolidation of testing platforms, the centralization of some services to a main or reference laboratory, and more robust processes to control utilization of laboratory testing. These initiatives will be accompanied by increasing consolidation within the laboratory industry. Parallel phenomena that may result and may be viewed as risks to the current operation of laboratory medicine or as opportunities for growth for those prepared to provide services within the new paradigm include the "commoditization" of laboratory services, "consumerism" self-directed healthcare, and direct-access testing.

While pathology and laboratory medicine were traditionally based on phenotypic, quantitative, and morphological observations, they are increasingly being augmented with immunophenotypic, genetic-proteomic, and molecular diagnostic results. All of these will be linked by increasingly sophisticated information systems that will integrate alphanumeric, graphic, and digital data in real time. Thus, the paradigm will shift from morphological and other classification schemata based on laboratory data to classification hierarchies that recognize biological heterogeneity and clinical relevance with an increased emphasis on specific disease entities susceptible to targeted therapies ("companion diagnostics"). This transition between diagnostic approaches will lead to a greater interplay between the conventionally distinct branches of anatomic and clinical pathology. The time frame of these predictions will be influenced by the rate of technology development, the extent to which healthcare will develop as a social contract or will be replaced by a purely marketplace ethic, and external events seemingly unrelated to healthcare.

KEY POINTS

- Healthcare and laboratory medicine are governed by a complex interplay between political, social, economic, and regulatory considerations.
- The major regulations that guide the practice of laboratory medicine include CLIA '88, HIPAA, OSHA, and the Physician Self-Referral Law (Stark Law).
- Regulatory mandates, funding and payment restrictions, a changing medical model emphasizing effectiveness and evidence-based care, and technological advancements will significantly influence how laboratory medicine is practiced in the future.

GLOSSARY

Centers for Disease Control and Prevention (CDC) The federal public health agency within the Department of Health and Human Services with broad responsibility for disease detection, monitoring and prevention, epidemiology and statistics, and laboratory practice.

Centers for Medicare and Medicaid Services (CMS) The federal agency within the Department of Health and Human Services with primary responsibility for payment and payment standards for the Medicare and Medicaid programs.

Clinical Laboratory Fee Schedule (CLFS) Document outlining the cost of outpatient clinical laboratory services for Medicare. Costs are often established for a geographical area or set at a national limit. The fee schedule is updated yearly to account for inflation, or it can be modified by congressional legislation.

Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) Federal law and regulations constituting the foundation of oversight and accreditation of all laboratory testing in the United States.

Electronic health record (EHR) Digital version of a patient's medical record that allows for documents, laboratory results, imaging studies, and medication information to be instantly available to authorized users in a secure manner.

Emergency use authorization (EUA) Permission granted by the FDA to allow for the availability and use of an unapproved product such as diagnostic tests and therapeutic medications in times of health emergencies (e.g., pandemics).

Evidence-based medicine Approach to the teaching and practice of medicine that utilizes literature review and outcome-based studies of effectiveness and possible harm to patients, rather than tradition or anecdotal experience, to guide diagnostic and treatment interventions.

Federal Select Agent Program (FSAP) Program that oversees the possession, use, and transfer of biological select agents and toxins that have the potential to cause severe health threats to the public.

Health Insurance Portability and Accountability Act of 1996 (HIPAA) Federal regulations that established national standards for the protection of health information, set allowable uses and disclosures, and outlined criminal and civil penalties for improper use.

***In vitro* clinical tests (IVCT)** Proposed new category of medical products separate from medical devices included in the VALID Act that petitions for a premarket review by the FDA based on the degree of risk posed by a laboratory-developed test (i.e., IVCT).

Indirect provider Under the HIPAA regulations, an entity or individual (e.g., laboratory or pathologist) without a direct

本书版权归John Wiley & Sons Inc.所有

treatment relationship to a patient. The indirect provider delivers healthcare based on the orders of another physician and typically provides services or reports the diagnosis or results to the patient-facing physician.

Institute of Medicine (IOM) American, nonprofit, nongovernmental organization that works to provide unbiased, evidence-based, and authoritative information and advice in the field of health and medicine to decision makers, professionals, and the public at large. Since 2015, IOM has been known as the National Academy of Medicine (NAM).

Internal review board (IRB) Group whose function it is to review and monitor biomedical research involving human subjects to ensure the protection of the rights and welfare of patients enrolled in studies.

Laboratory-developed test (LDT) An *in vitro* test that is modified in some fashion from its FDA-approved indication or a test that is designed and implemented for patient diagnostic purposes by an individual laboratory without FDA review.

Merit-based Incentive Payment System (MIPS) Medicare program that evaluates eligible physicians on the following components in their specialty: quality, cost, promoting interoperability, and improvement activities. In 2022, maximum bonuses and penalties were set at 9% and −9%, respectively.

Occupational Safety and Health Administration (OSHA) Federal regulatory agency within the Department of Labor with primary responsibility to ensure safe and healthy working conditions, including protection against blood-borne pathogens for those with an occupational risk.

Physician Quality Reporting System (PQRS) Reporting program through CMS that used quality metrics to compare eligible professionals' performance to that of their peers and provided incentive payments for demonstrated performance of certain indicators and penalties if metrics were not achieved. In 2017, PQRS transitioned to the Merit-based Incentive Payment System (MIPS).

Physician Self-Referral Law (Stark Law) Federal regulations prohibiting referral of laboratory and other health services to entities in which the referring physician or an immediate family member has a financial interest.

Protected health information (PHI) Personal medical details that receive federal protection by the HIPAA Privacy Rule, which gives patients a set of rights with respect to their health information while permitting disclosure for necessary patient care and billing activities.

U.S. Food and Drug Administration (FDA) Regulatory body under the Department of Health and Human Services that is responsible for protecting public health by ensuring the safety, efficacy, and security of food, medications, medical devices, and biologic products (e.g., blood products and vaccines).

REFERENCES

1. **Kundera M.** 20 May 2002. The great return. *The New Yorker*.

2. **Osler W.** 1961. *Sir William Osler Aphorisms: From His Bedside Teachings and Writings*. Charles C Thomas, Springfield, IL.

3. **Roser M**. 2020. Why is life expectancy in the US lower than in other rich countries? https://ourworldindata.org/us-life-expectancy-low. Accessed 14 May 2022.

4. **Supreme Court**. 2021. No. 19-840. *California v. Texas*. https://www.supremecourt.gov/opinions/20pdf/19-840_6jfm.pdf. Accessed 14 May 2022.

5. **Cohen WJ**, **Ball RM**. 1965. Social Security Amendments of 1965: summary and legislative history. https://www.ssa.gov/policy/docs/ssb/v28n9/v28n9p3.pdf. Accessed 14 May 2022.

6. **100th Congress**. 1988. Public Law 100-578—Oct. 31, 1988. 102 Stat. 2903. Clinical Laboratory Improvement Amendments of 1988. https://www.govinfo.gov/content/pkg/STATUTE-102/pdf/STATUTE-102-Pg2903.pdf. Accessed 14 May 2022.

7. **U.S. Congress**. 1967. 81 Stat. 536, Public Law 90-174, Sec. 5. https://www.govinfo.gov/content/pkg/STATUTE-81/pdf/STATUTE-81-Pg533.pdf. Accessed 14 May 2022.

8. **Duncan H.** 2008. An update on the Clinical Laboratory Improvement Amendments of 1988. *Lab Med* **39**:69–72.

9. **Yost J.** 2012. CLIA update: what's on the agenda for 2012? *Natl Intell Rep* **12**:4–7.

10. **Evans JP**, **Berg JS**. 2011. Next-generation DNA sequencing, regulation, and the limits of paternalism: the next challenge. *JAMA* **306**: 2376–2377.

11. **Hudson KL**. 2011. Genomics, health care, and society. *N Engl J Med* **365**:1033–1041.

12. **Food and Drug Administration**. 2015. The public health evidence for FDA oversight of laboratory developed tests: 20 case studies. http://wayback.archive-it.org/7993/20171115144712/https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM472777.pdf. Accessed 14 May 2022.

13. **O'Sullivan J**. 2007. Medicare: physician self-referral ("Stark I and II"). https://web.archive.org/web/20120402205453/http://aging.senate.gov/crs/medicare19.pdf. Accessed 14 May 2022.

14. **Bierig JR**. 2002. Liability and payment issues in the selection of pathology assays. *Arch Pathol Lab Med* **126**:652–657.

15. **Mitchell JM**. 2012. Urologists' self-referral for pathology of biopsy specimens linked to increased use and lower prostate cancer detection. *Health Aff (Millwood)* **31**:741–749.

16. **Institute of Medicine**. 1999. *To Err Is Human: Building a Safer Health Care System*. National Academies Press, Washington, DC.

17. **James JT**. 2013. A new, evidence-based estimate of patient harms associated with hospital care. *J Patient Saf* **9**:122–128.

18. **Rodziewicz TL**, **Houseman B**, **Hipskind JE**. 2022. Medical error reduction and prevention. StatPearls Publishing, Treasure Island, FL. Accessed 14 May 2022.

19. **Brennan TA**, **Gawande A**, **Thomas E**, **Studdert D**. 2005. Accidental deaths, saved lives, and improved quality. *N Engl J Med* **353**:1405–1409.

20. **Berwick DM**, **Leape LL**. 1999. Reducing errors in medicine. *BMJ* **319**:136–137.

21. **Leape LL**, **Berwick DM**. 2005. Five years after To Err Is Human: what have we learned? *JAMA* **293**:2384–2390.

22. **Fung CH**, **Lim YW**, **Mattke S**, **Damberg C**, **Shekelle PG**. 2008. Systematic review: the evidence that publishing patient care performance data improves quality of care. *Ann Intern Med* **148**:111–123.

本书版权归John Wiley & Sons Inc.所有

23. Wachter RM, Foster NE, Dudley RA. 2008. Medicare's decision to withhold payment for hospital errors: the devil is in the details. *Jt Comm J Qual Patient Saf* **34**:116–123.

24. Leape LL, Berwick DM, Bates DW. 2002. What practices will most improve safety? Evidence-based medicine meets patient safety. *JAMA* **288**:501–507.

25. Spackman K. 2002. SNOMED CT unlocks the power of clinical data for pathologists. *Lab Med* **33**:263–266.

26. Wilson ML. 2002. Education and training: practice makes perfect. *Am J Clin Pathol* **118**:167–169.

27. Davis Giardina T, Singh H. 2011. Should patients get direct access to their laboratory test results? An answer with many questions. *JAMA* **306**:2502–2503.

28. Iglehart JK. 2011. The uncertain future of Medicare and graduate medical education. *N Engl J Med* **365**:1340–1345.

29. Campbell EG. 2009. The future of research funding in academic medicine. *N Engl J Med* **360**:1482–1483.

30. Sekar K. 2021. National Institutes of Health (NIH) funding: FY1996-FY2022. https://sgp.fas.org/crs/misc/R43341.pdf. Accessed 14 May 2022.

31. American Society for Clinical Pathology. The medical laboratory personnel shortage. https://www.ascp.org/content/docs/default-source/policy-statements/ascp-pdft-pp-med-lab-personnel-short.pdf?sfvrsn=2. Accessed 14 May 2022.

APPENDIX 45.1 Websites

College of American Pathologists
Description of CAP's standards for accreditation for its biorepository program.
https://www.cap.org/laboratory-improvement/accreditation/biorepository-accreditation-program. Accessed 14 May 2022.

Federal Select Agent Program
Organization that oversees the possession, use, and transfer of biologic select agents that could potentially be utilized for bioterrorism and cause a significant public health risk.
https://www.selectagents.gov/index.htm. Accessed 14 May 2022.

U.S. Department of Health and Human Services
Federal rules concerning patient privacy regulations contained in HIPAA law.
https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html. Accessed 14 May 2022.

United States Department of Labor
Federal rules concerning prevention of infection with blood-borne pathogens.
https://www.osha.gov/bloodborne-pathogens. Accessed 14 May 2022.

本书版权归John Wiley & Sons Inc.所有

46

Introduction
A Profession Defined by a Pandemic
Educating the Workforce: Challenges and Opportunities
Emerging Roles of the Clinical Scientist
Emerging Laboratory Management Considerations with the Clinical Scientist
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENTS
REFERENCES

The Future of the Clinical Scientist Workforce

I. J. Frame, Donna Gaffney, and Jana Bagwell

OBJECTIVES

Describe how the COVID-19 pandemic has affected the diagnostic laboratory workforce

Outline challenges in how the clinical scientist is educated

List emerging skills that future clinical scientists will use to augment their value in patient care

Identify ways laboratory managers can adjust to the changing clinical scientist workforce

> *No work is insignificant. All labor that uplifts humanity has dignity and importance and should be undertaken with painstaking excellence.*
>
> Martin Luther King, Jr.

THE CLINICAL SCIENTIST WORKFORCE is at a unique point in its history. On the one hand, the workforce's importance in society earned recognition in the early phase of the COVID-19 pandemic as clinical and public health laboratories met diagnostic testing needs during a public health emergency. On the other hand, the challenges facing the profession in terms of compensation, education, and duties accelerated and were exacerbated as the pandemic progressed.

The clinical scientist is a dynamic and exciting professional who has the potential to touch the lives of many patients—in some cases, touch the lives of even more patients than physicians and nurses would see over their careers. The diagnostic laboratory is a complex work environment that employs a variety of individuals with varying amounts of education and expertise. The clinical scientist workforce who are employed in diagnostic laboratories will continue to evolve, but some of the core staff roles have historically included:

- Phlebotomy technicians; phlebotomists
- Histologic technicians; histotechnicians
- Histologic technologists; histotechnologists
- Cytotechnologists
- Medical Laboratory Assistants
- Clinical/Medical Laboratory Technicians (MLTs)

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch46.

本书版权归John Wiley & Sons Inc.所有

- Clinical Laboratory Scientists (CLSs); Medical Technologists (MTs); Medical Laboratory Scientists (MLSs)
- Laboratory specialists (e.g., cytogenetics, molecular diagnostics, esoteric testing)
- Pathologist assistants
- Doctoral-level laboratory scientists, directors, pathologists
- Administrators

Most of this chapter's contents apply to all positions within the diagnostic laboratory, and the term "clinical scientist" is used broadly to encompass all members of the laboratory team. The focus, however, is on the "bench-level" scientists who are involved predominantly in the analytic/examination phase of the testing cycle, as these individuals form the largest percentage of the profession. The first half of the chapter focuses on the challenges confronting the clinical scientist workforce and education. The second half of the chapter focuses on new and emerging roles the clinical scientist is uniquely qualified to fill and how the laboratory management team can capitalize on those skills to foster a thriving clinical scientist workforce.

A Profession Defined by a Pandemic

As the SARS-CoV-2 virus started circulating at the end of 2019, the world looked toward diagnostic laboratories to roll out high-quality testing to help identify patients positive for SARS-CoV-2. For a moment, it seemed that diagnostic laboratories and the people who worked in them were putting forth heroic efforts to help fight and contain the deadly and contagious virus by providing high-quality diagnoses. Early data from the first 2 months of the pandemic suggested that morale was either improving or unchanged, and that the amount of overtime worked in the laboratory actually was decreasing (1). But as the pandemic progressed, the challenges that had previously existed in diagnostic laboratories began to reemerge. These existing problems included the following: wages across all levels of clinical scientists were lower than for their clinical counterparts, particularly in rural areas; staffing adequacy was insufficient, with extended periods of time to fill vacancies, especially supervisory positions; and education programs had already been on the decline, causing fewer graduates to enter the workforce (2–5). So as the public's appetite for SARS-CoV-2 testing expanded throughout the pandemic, the challenges that had already been facing the laboratory began to be magnified.

One such challenge that was highlighted was the aging workforce (4). At the beginning of the pandemic, the average age of the clinical scientist across the United States tended to be older. Since older age was a defined risk factor for COVID-19, many chose to leave the profession for their own safety, or may have been forced to leave due to their own illness.

While an aging workforce was certainly a challenge, another important stressor facing the clinical scientist workforce was burnout (6). A 2018 survey from the American Society for Clinical Pathology showed that a staggering 85.3% of laboratory professionals reported feelings of burnout at some point in their career, and that roughly half felt that burnout was a current problem (7). The top issues that contributed to burnout in that survey were inadequate staffing; being overworked; unsupportive management; scheduling; and lack of respect (7). While these areas were already identified as contributors prior to the pandemic, they were intensified as the pandemic started.

An imbalance of workload in the diagnostic laboratories was created as testing volumes increased, particularly for SARS-CoV-2-related diagnostics. Some specialists from other areas may have been pulled to help with SARS-CoV-2 sample receiving, processing, testing, and reporting. This left more work for others as workloads increased and fewer people were performing those tasks. Many laboratories relied on "forced" overtime shifts to accommodate the increased workload in critical areas. One sentiment among workers was that quantity/productivity of testing was all that mattered, not quality. Confronted with ever-increasing work volumes, workers either were leaving positions for higher-paying positions at competing institutions, or simply left the profession altogether (8).

Other important factors leading to clinical scientists leaving the workforce had to do with perceived lack of respect from other members of healthcare teams (9). Although not necessarily new, sentiments of being "invisible" and being disrespected by physicians and nurses may have been exacerbated during the pandemic as demands for testing increased. As clinical scientists exited the profession due to either age, health, or burnout, one of the more pressing issues that came to light was how this resigning workforce would be replaced. Now, more than ever, the gaps and challenges of the clinical scientist education system were made readily apparent.

Educating the Workforce: Challenges and Opportunities

Programs in laboratory science, cytotechnology, histotechnology, and other laboratory-based programs have been decreasing in number (4). The reasons for this are many, including perceived decreased value in institutes of higher learning; decreased demand for students entering the programs; lower compensation compared to other healthcare workers; and lack of visibility in the profession. Regardless of the cause, the result is insufficient numbers of graduates to fill open positions. The number of medical laboratory scientist and technician (MLS/MLT) positions is expected

本书版权归John Wiley & Sons Inc.所有

to increase by 11% through the year 2030, which is a faster rate than the average for all occupations, according to the Bureau of Labor Statistics (10). The pandemic also presented unique challenges to these education programs: many students were forced to adopt virtual learning immediately. Strained laboratory staffing also created a weak clinical experience, due to decreased available workforce to ensure an adequate clinical experience. In some programs, there were graduates who did not have direct bench-related training and training was conducted virtually (11). This likely negatively impacted students' educational experience.

To address the challenges of clinical scientist education, a multifaceted approach will need to be used. Foremost, professional societies and leaders at the university, hospital, municipal, and political levels will need to continue advocacy efforts for the profession. Advocacy efforts will be broad but will likely include various financial incentives to recruit individuals into the profession. Recruitment may involve traditional approaches, such as scholarships and loan forgiveness. Similarly, university-based programs will need to continually assess their strategic plan to maintain viability (12). Other recruitment methods may need novel approaches. Virtual reality platforms are being deployed as methods for training staff, such as the CDC's Division of Laboratory Systems (13). One could imagine using virtual or augmented reality laboratory simulations in high-school classrooms to demonstrate the unique niche of the clinical scientist and the educational opportunities that dedicated programs have to offer.

In addition to traditional 2- and 4-year programs leading to a credentialed professional degree/certificate, there will continue to be other methods of educating clinical scientists. One such model is the hospital-based program that will take students with 4-year science degrees and provide 1- to 2-year intensive laboratory rotations. Programs specializing in MLT-to-MLS transitions will also continue to be a mechanism for clinical scientists to advance their education and training. These credentialed individuals will continue to provide high-quality testing in the clinical laboratories, as credentialed professionals are associated with higher acceptable proficiency testing result rates compared to non-credentialed professionals (14). Credentials also open the doors for career advancement, as certification is associated with professional advancement compared to non-certified staff (15).

Outside of dedicated programs, many laboratories will recruit individuals who have sufficient educational credentials to perform CLIA-designated waived-, moderate-, and high-complexity testing, but do not hold a degree or certification/licensure in a laboratory science. For example, according to the Code of Federal Regulations, high-complexity testing personnel who do not hold a degree in laboratory science must have at least 60 semester hours, many of which must be from the biological and chemical sciences. Furthermore, such individuals must have at least 3 months of documented laboratory training in each specialty where high-complexity testing will take place. With fewer credentialed graduates of dedicated clinical scientist programs to fill expanding vacancies, various healthcare entities will increasingly rely on non-credentialed employees to join their institutions. In some states, this pathway is not an option, as licensure may be a prerequisite prior to performing high-complexity testing. Challenges will exist to fully qualify these individuals who lack laboratory science degrees to meet the standards of credentialing agencies and certification examinations.

Emerging Roles of the Clinical Scientist

The clinical scientist will continue to be an expert in collecting, receiving, preparing, and analyzing patient specimens and reporting test results. While these tasks will always be at the core of the clinical scientists' roles, the changing landscape of healthcare and the clinical laboratories requires new skillsets to be adopted by the clinical scientist at all levels. These new skillsets will address the needs of healthcare institutions but may indeed be mechanisms to recruit and retain clinical scientists who perform valuable and meaningful work.

One of the prominent roles that the clinical scientist will need to fill is that of laboratory consultant (16–18). The clinical scientist has long been a reference for nursing and physician staff needing urgent information about specimen collection devices, methods, and interpretations of test results and comments (17). The new consultation roles place the clinical scientist in treatment teams, hospital-based quality committees, community outreach programs, and other positions.

The concept of placing clinical scientists within patient treatment teams encourages interpretation and analysis of laboratory testing in real time with other members of the interdisciplinary care team, including physicians, nurses, advanced practice providers, pharmacists, rehabilitative services, social workers, and others. The model has been applied successfully in many inpatient hospital settings, and many have been coined "Ambassador Programs."

At one of our institutions, the Ambassador Program laboratory staff visited select units twice weekly and found that a major benefit of the program was that it fostered positive relationships between nursing staff and the laboratory, notably by improving communication. There was reciprocal opportunity for the laboratory staff to experience the clinical setting and for the nursing/care-giving staff to experience the laboratory setting. The challenges of the program included having sufficient time away from the laboratory to sufficiently train for the program and having sufficient time to spend with the

本书版权归John Wiley & Sons Inc.所有

clinical teams in addition to maintaining laboratory responsibilities. Nevertheless, the Ambassador Program was viewed positively and was an opportunity for laboratory staff to engage with their work beyond the activities of the laboratory (19). Analysis of how Ambassador Programs have affected healthcare outcomes appears to be a much needed area of research.

While not every inpatient hospital setting has the capacity to provide a clinical scientist Ambassador Program, the model will continue to provide high-quality care for patients. Improving patient care is certainly a worthwhile reason to have such programs, but having competent, knowledgeable clinical scientists acting as consultants will also serve as visibility to hospital leadership. Such roles will highlight the value a clinical scientist has beyond the scope of processing patient specimens.

In similar capacity to Ambassador Programs, clinical scientists of the future will provide increased representation in various hospital, clinic, and public health quality committees. Examples of such committees presently include Infection Prevention & Control, Pharmacy & Therapeutics committees, Antimicrobial Stewardship programs, and Institutional Safety. Future committees may focus on Emerging Threats, Disaster Planning, and various administrative/financial committees.

One important emerging initiative seen in many healthcare entities throughout the United States is the Diagnostic Stewardship Program. The goal of many Diagnostic Stewardship Programs is to assist ordering providers with appropriate use of laboratory diagnostics to help improve quality of patient care and reduce costs (20). Such committees use society guideline recommendations and best practices and track laboratory test utilization and costs. Many professionals in healthcare can inform Diagnostic Stewardship Programs with their perspectives and viewpoints, including pathologists, ordering providers, nursing staff, pharmacists, and others. The clinical scientist, however, is uniquely qualified to inform and, in fact, lead such initiatives. Clinical scientists provide invaluable knowledge to a Diagnostic Stewardship Program. They are familiar with assay performances, analytical details, and important limitations of an institution's specific assays, and they have an analytical mindset. Furthermore, they are intimately aware of an institution's testing volumes and vendor contracts and how data are stored in the laboratory information systems, all of which are important information needed for a successful Diagnostic Stewardship Program.

In addition to consultant roles, a key role clinical scientists will continue to play in the future is as a key communicator with vendors of laboratory and technical instrumentation and systems. Analyzers, computation/interface systems, and the clinical laboratory continue to increase in complexity: more instruments increasingly rely on automation and sophisticated software that may be prone to increased downtimes compared to less advanced instrumentation. Given this, the clinical scientist will need to be able to communicate clearly and succinctly with technical and engineering support staff to troubleshoot problems when they arise in instrumentation downtimes. Creative thinking will also be an essential skill as novel instruments and analyzers are introduced into the market and may require novel solutions that are not used in current methods.

As technology continues to advance in the clinical laboratory, the corresponding knowledge base for navigating and using laboratory information systems and data warehouses will also continue to expand. Bench-level scientists will be expected to adapt and interact with the increasingly complex world of clinical informatics. Although this may sound intimidating to some of today's clinical scientists, advances in clinical informatics may help bench scientists with their daily tasks. Clinical informatics may be able to harness the power of large data sets to perform analyses such as evaluating assay performance and statistics in an automated format; determining test utilization across multiple sites in a large health system; and systematically tracking laboratory supply inventory. Data analytics and data visualizations will, therefore, be increasingly important tools for the future clinical scientist. Some clinical scientists may enjoy these aspects of clinical informatics so much that they may choose to advance their career away from the clinical laboratory to the field of information technology in roles such as analysts and applications specialists (21). Such analysts with a laboratory science background will be essential in shaping the next iteration of clinical informatics for the clinical laboratory.

Clinical scientists will not only be essential in advancing informatics, but will also continue to play a crucial role in bench-side research and development. The clinical scientist perspective will be invaluable at every step of the development process. Non-hospital/non-clinical-laboratory roles for clinical scientists include roles at basic science research laboratories, biotech startups, *in vitro* diagnostic companies, and regulatory agencies. Once products are in the market, the clinical scientists who are staffed inside hospital and clinical laboratories will similarly play essential roles in method development and validation at their sites, assuring that good laboratory practices and local regulations/accreditation standards are followed.

Technical, technologic, and scientific aspects of the clinical scientist's duties may indeed attract many into the profession; however, there are numerous other skills that will be required of tomorrow's clinical scientist (21). Knowledge of basic budgetary and fiscal skills will certainly prove essential. These skills include negotiation with sales representatives; understanding the components of a successful purchasing contract; understanding laboratory

本书版权归John Wiley & Sons Inc.所有

supply management; and learning how and whom to advocate for additional staff. Though some of these tasks may fall under the responsibilities of the clinical scientists' supervisors, managers, and directors, having the perspective of a well-trained clinical scientist in these processes has valuable benefits. By fulfilling these tasks, clinical scientists will gain useful skills as they advance their careers, and they may be able to provide assistance to those with administrative roles in the laboratory.

One final field that the clinical scientist of the future will need is skill development in the field of laboratory quality assurance. Running a high-quality laboratory should be in the "spirit" of all clinical scientists, and surely all clinical scientists wish to produce accurate, reliable, and informative results for patients. As the regulatory landscape continues to evolve over time, the laboratory scientist is in a unique position to inform how a laboratory can continue to improve, monitor, and maintain high standards. It is vital that supervisors, managers, and directors who oversee the clinical scientists listen to what their staff say. Often it is the laboratory scientist who is the first to point out problems, and they are often the first to offer solutions.

Emerging Laboratory Management Considerations with the Clinical Scientist

The clinical scientist of the future will continue to evolve, and the dynamics that will shape that evolution are readily emerging. Multiple inputs and stressors are affecting the system and require careful consideration by laboratory supervisors, managers, and directors who work closely with the clinical scientist.

The most discussed and relevant factor affecting the clinical scientist workforce dynamics today, by far, is compensation (2). All laboratories will need to find ways to augment the current clinical scientists' wages. The wages of clinical scientists are often compared to those of other critical healthcare specialists who achieve similar levels of education, such as nursing and respiratory therapy. On average, the laboratory scientist makes substantially decreased wages (22).

Throughout the COVID-19 pandemic, each of those three professions (nursing, respiratory therapy, and laboratory) experienced dramatic changes in employment numbers as the demand for these professionals far outpaced the supply. In order to address staffing shortages in critical areas, employment agencies for "traveling" professionals expanded their numbers, and eventually traveling laboratory scientists became prevalent throughout the industry. Similarly, institutions were forced to increase wages for their existing laboratory scientists to keep current staff from going to other institutions or travel agencies. Though some institutions were able to maintain adequate staffing, many were faced with unprecedented staffing shortages. The effects of these shortages continue to plague many clinical laboratories well into 2023, well over 3 years since the onset of the COVID-19 pandemic.

The important lesson learned is that salary disparities between traveling staff and permanent staff were unsustainable. The reasons were both obvious and subtle. Some traveling professionals made more than two, three, or four times the wages of permanent staff. These wages strained already-constrained operating budgets. The traveling staff were simply not as well experienced as the permanent staff in the institutional policies and procedures, and the permanent staff not only were expected to perform their own tasks but were expected to train traveling staff who were receiving more money. Even within permanent staff, some laboratory scientists in areas that experienced shortages (for example, staff directly associated with SARS-CoV-2 testing) were offered substantial pay differentials for retention, while scientists in other areas may not have received the pay differentials.

Despite the origin of pay disparities, such wage practices are not sustainable for the long term, and ways to normalize competitive wage practices need to be strategized. Laboratory administration must find ways to eliminate artificial disparities. For example, expiration dates for traveler contracts must be made clear and adhered to. Supervisors, managers, and directors must advocate at multiple levels of institutional management for increased compensation and staffing positions, where indicated. Institutional policies for accurate and transparent presentation of compensation data for clinical scientists across all areas may also be of benefit. Finally, outlining clear levels/career ladder milestones to achieve with graduated wage levels may also improve morale and work ethic, and may indeed induce clinical scientists to remain in the profession and stay with employers.

Benefits beyond base salary may also contribute to a sustainable and consistent workforce. Some examples include:

- Providing adjustments to assigned shift hours to accommodate familial or educational responsibilities
- Offering on-site fringe benefits, such as childcare and educational opportunities
- Permitting work-from-home options if such opportunities are possible within a scientist's work area
- Continuing to offer differentials for shifts worked during evenings, nights, weekends, and holidays
- Distributing engaging/interesting/meaningful work in evening and night shifts. Examples of this work could include quality improvement projects, quality assurance activities, method development and validation, and employee engagement strategic planning.
- Offering competitive retirement, healthcare, and other fringe benefits

本书版权归John Wiley & Sons Inc.所有

Inclusion of such benefits may persuade a clinical scientist to remain in the profession.

Training and recruiting clinical scientists from within one's country is ideal; however, recruiting clinical scientists from international sources may become more commonplace. Every country in the world needs a clinical scientist workforce, and training programs exist throughout. The American Society for Clinical Pathology offers the International Credential Maintenance Program (CMP) for dedicated individuals seeking certification, which demonstrates that an individual has achieved high-level skill sets suitable to work in clinical laboratories of many countries. There are recruiting agencies that may contract with healthcare entities to facilitate hiring of such international workers. These agencies often facilitate recruitment and visa consultations with the contracting laboratory. Two important challenges for laboratory management who hire international workers are (i) to figure out how to smoothly integrate an internationally recruited individual to work within the existing cultural conventions of their work environment and (ii) to ensure that internationally trained workers are supported to understand expectations of professionalism and communication in their new environment. Another important consideration is to ensure the recruiting agencies are not facilitating "brain drain," in which valuable intellectual talent is being shuttled away from originating areas where it is much needed. The clinical laboratory historically attracts talent from all over the world, and hiring in this space may expand in the future clinical scientist workforce.

The current clinical science workforce is aging. As the current workforce retires, many open positions will necessarily need to be filled by younger generations. The workplace values of so-called "Millennials," "Generation Y," and "Generation Z" (referring to employees born after 1980) may differ substantially from those of older employees, and managers will need to be equipped to understand these values to ensure the successful recruitment, retention, and advancement of their younger employees (23).

Younger workers may place greater emphasis on variables not previously considered by older generations when deciding where to work. Some "intrinsic" work values that are sought by younger generations include "helping others" and "doing challenging work" (23). Institutional values and a need to work on social causes that are personal to them appear to play an important role in where younger workers choose employment. Similarly, if work environments shift away from their currently held values, younger people may feel more empowered to seek other employment, as younger generations are mobile and no longer confined to geographic regions.

Management styles when working with younger generations may differ from models previously used. Managers may find that younger employees want more one-on-one interaction, oversight, and feedback provided by the direct supervisor (23). Encouragement and feedback at regular intervals rather than a single annual performance appraisal may become more commonplace in order to accomplish short- and long-term goals. Younger workers value a teamwork approach to policy- and decision-making, rather than supporting a directive from management. Of course, not all leadership styles need to be changed to accommodate younger employees. Effective management, however, will need to be aware of these differing perspectives from younger members of their team.

One final consideration that will be key for the future of the laboratory workforce will be encouraging and providing ample opportunity for meaningful continuing education. Scientists are naturally inquisitive and have a thirst for discovering new knowledge and applying it to patient care. It is simply insufficient to provide passive computer-based modules to achieve adequate hours to maintain certification. Truly engaging, active education will have more meaning and could be a tool for recruitment and retention. Opportunities to lead quality-improvement and research projects may be rewarding endeavors and are within the abilities of clinical scientists. Presenting their findings at national/international meetings may provide essential networking and eye-opening experiences, and such pursuits should be encouraged where feasible. Even if such pursuits are not financially or logistically viable, expanding knowledge in the fields of regulation and compliance will improve the knowledge of "why" we need to follow quality initiatives. Ultimately, the laboratory scientist who is engaged in his or her own education will serve as an example and inspiration for new laboratory scientists and students.

SUMMARY

The challenges of today's clinical scientist workforce have been highlighted during the COVID-19 pandemic. In order to emerge from the challenges of burnout, decreasing numbers of professionals, and shrinking education programs, laboratory managers of the future will need to provide engaging and meaningful opportunities for clinical scientists to broaden their skillsets, to motivate workers to continue work in the laboratory and beyond, and to attract talented individuals into the profession. The supervisors, managers, and directors who work with clinical scientists will need to find ways to emphasize the value of the clinical scientists' work in a workforce that is increasingly diverse in educational background, age, and national origin. As laboratory management acknowledges the challenges that the current diagnostic laboratory faces and embraces novel ways to address those challenges, the future of the clinical scientist profession will be exciting and sustainable.

本书版权归John Wiley & Sons Inc.所有

KEY POINTS

- The COVID-19 pandemic has affected the clinical scientist workforce by emphasizing the preexisting challenges of competitive compensation, decreased staffing levels, an aging workforce, and burnout.
- Educating the clinical scientist continues to evolve, as university-based programs continue to face challenges of recruitment and (during the pandemic) finding suitable clinical opportunities for their trainees. Alternative pathways to becoming a certified clinical scientist will become more prevalent if the workforce supply will meet the demands.
- The clinical scientists of the future will continue to be the experts in laboratory diagnostic testing; however, additional roles will be adopted for improving patient care, employee satisfaction, and professional advancement. Such roles include clinical consultant, institutional committee engagement, information systems and data analytics, and other research and development fields.
- Laboratory management will embrace the evolving nature of the clinical scientist to ensure adequate recruitment and retention of staff. This includes offering competitive and equitable compensation, recruiting international workers, modifying management methods amenable to a younger workforce's values, and providing meaningful continuing education.

GLOSSARY

CDC Centers for Disease Control and Prevention. The federal public health system for the United States.

CLIA Clinical Laboratory Improvement Amendments of 1988. Federal regulations and standards for testing human specimens for healthcare purposes in the United States.

COVID-19 Coronavirus disease 2019, a clinical syndrome caused by SARS-CoV-2 with multiple clinical presentations, notably respiratory illness.

Clinical scientist A general term for all members of the laboratory testing team involved in preexamination, examination, and postexamination phases of the testing cycle.

Medical Laboratory Scientist (MLS) Also known as a Clinical Laboratory Scientist and Medical Technologist, the MLS is a laboratory professional having at least a bachelor's-level degree in laboratory science, or an individual with a bachelor's-level degree in other fields who has completed additional laboratory-specific training. Advanced degrees at the master's and doctoral level are available. Expertise may be general or subspecialized in numerous clinical laboratory fields. Board certification as an MLS, technologist, or specialist may be possible. Certification and licensure requirements to work as an MLS are dependent on institutional policies and state regulations.

Medical Laboratory Technician (MLT) A laboratory professional with at least a 2-year associate's level degree and training in laboratory science. Certification and licensure requirements to work as an MLT are dependent on institutional policies and state regulations.

SARS-CoV-2 Severe acute respiratory syndrome coronavirus type 2, the causative agent of the COVID-19 pandemic.

ACKNOWLEDGMENTS

We thank Diana Mass and John R. Snyder, who authored this chapter for the 2nd edition of this text, for providing an excellent foundation for our work. Their words are still true for the future of the clinical scientist workforce. We also thank all of the clinical scientists who work every day to bring high-quality and life-changing diagnostic test results to patients around the world.

REFERENCES

1. **Nuñez-Argote L, Baker DP, Jones AP**. 2021. Initial clinical laboratory response to COVID-19: a survey of medical laboratory professionals. *Lab Med* **52**:e115–e124.

2. **Garcia E, Kundu I, Fong K**. 2021. American Society for Clinical Pathology's 2019 wage survey of medical laboratories in the United States. *Am J Clin Pathol* **155**:649–673.

3. **Garcia E, Kundu I, Kelly M, Soles R**. 2019. The American Society for Clinical Pathology's 2018 vacancy survey of medical laboratories in the United States. *Am J Clin Pathol* **152**:155–168.

4. **American Society for Clinical Laboratory Science**. 2018. Position Paper: Addressing the Clinical Laboratory Workforce Shortage. https://ascls.org/addressing-the-clinical-laboratory-workforce-shortage/. Accessed 3 March 2022.

5. **American Society for Clinical Pathology**. Policy Statement: The Medical Laboratory Personnel Shortage. https://www.ascp.org/content/docs/default-source/policy-statements/ascp-pdft-pp-med-lab-personnel-short.pdf. Accessed 11 March 2022.

6. **Miller J.** 2021. Your burnout is real. *Clin Lab News* **47**:10–13.

7. **Garcia E, Kundu I, Kelly M, Soles R, Mulder L, Talmon GA**. 2020. The American Society for Clinical Pathology's job satisfaction, well-being, and burnout survey of laboratory professionals. *Am J Clin Pathol* **153**:470–486.

8. **Chiou PZ**. 2021. Exploring staff turnover, burnout, and resilience in cytology reference laboratories: a workforce qualitative study. *Cytopathology* **32**:738–750.

9. **Garcia E, Kundu I, Kelly M, Guenther G, Skillman S, Frogner B**. 2021. Focus group results, p. 32–41. *In The Clinical Laboratory Workforce: Understanding the Challenges to Meeting Current and Future Needs*. American Society for Clinical Pathology & Center for Health Workforce Studies, Washington, DC.

10. **Bureau of Labor Statistics**. 2023. U.S. Department of Labor, Occupational Outlook Handbook, Clinical Laboratory Technologists and Technicians. https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm. Accessed 30 June 2022.

11. **Garcia E, Kundu I, Kelly M, Guenther G, Skillman S, Frogner B**. 2021. Discussion and next steps, p. 50–57. *In The Clinical*

本书版权归John Wiley & Sons Inc.所有

Laboratory Workforce: Understanding the Challenges to Meeting Current and Future Needs. American Society for Clinical Pathology & Center for Health Workforce Studies, Washington, DC.

12. Behan KJ. 2021. Strategies for sustainability of university-based medical laboratory sciences programs. *Lab Med* **52**:420–425.

13. Centers for Disease Control and Prevention. 2021. Virtual reality laboratory training. https://www.cdc.gov/labtraining/vr.html. Accessed 1 July 2022.

14. Delost MD, **Miller WG**, **Chang GA**, **Korzun WJ**, **Nadder TS**. 2009. Influence of credentials of clinical laboratory professionals on proficiency testing performance. *Am J Clin Pathol* **132**: 550–554.

15. Chiou PZ, **Jia Y**. 2022. Influence of certification on a pathology laboratory professional's career mobility. *Am J Clin Pathol* **157**: 942–947.

16. Mass D, **Snyder J**. 2014. The future of the clinical scientist workforce, p 907–917. *In* Garcia L (ed), *Clinical Laboratory Management*, 2nd ed. ASM Press, Washington, DC.

17. American Society for Clinical Laboratory Science. 2021. Position Paper: Value of Clinical Laboratory Services in Healthcare. https://ascls.org/value-of-clinical-laboratory-services/. Accessed 1 July 2022.

18. Odegard A. 2022. The value of building relationships with services outside the lab. *Clin Lab Man* **14**:9–11.

19. Hutson L. 2019. A network model of communication and test utilization: a laboratory ambassador program. *Am J Clin Pathol* **152** (Suppl 1):S146.

20. Hueth KD, **Prinzi AM**, **Timbrook TT**. 2022. Diagnostic stewardship as a team sport: interdisciplinary perspectives on improved implementation of interventions and effect measurement. *Antibiotics (Basel)* **11**:11.

21. Ross N. 2022. Career opportunities beyond the lab bench. *Clin Lab Man* **14**:18–21.

22. Leber AL, **Peterson E**, **Dien Bard J**, **Personnel Standards and Workforce Subcommittee, American Society for Microbiology**. 2022. The hidden crisis in the times of COVID-19: critical shortages of medical laboratory professionals in clinical microbiology. *J Clin Microbiol* **60**:e0024122.

23. Maloni M, **Hiatt MS**, **Campbell S**. 2019. Understanding the work values of Gen Z business students. *Int J Manag Educ* **17**:100320.

本书版权归John Wiley & Sons Inc.所有

47

Introduction
Electronic Health Records
Definition and Components • Status of EHR Use
Federal Regulations Related to EHRs and Their Implications for Laboratories
Meaningful-Use Requirements Directly Relevant to Laboratories • EHR Certification • Certification Criteria and Standards Most Relevant to Laboratories
Concerns and Implications for Laboratories Related to Increased Use of EHR Systems
Potential Consequences • Laboratory Reports • "Order Set" Challenges • Information Overload • Formatting Incompatibilities
Results Management
Laboratory Report Components • Laboratory Report Retrieval • Cumulative Laboratory Results • Laboratory Data Display Issues • Validation of EHR Laboratory Report Displays • Physician Alerts • Laboratory Test Result Delivery in an Integrated Healthcare Network
Computerized Provider Order Entry
Introduction • CLIA '88 Required Laboratory Test Request Elements • Appropriate Choice of Individual Laboratory Test Names
EHR-LIS Interfaces
Technical Aspects of Interfaces: HL7 and LOINC • Operational Challenges for Laboratories with LIS-EHR Interfaces
Tactics for Working with EHR Support Staff
Laboratory Involvement in EHR Selection and Implementation
SUMMARY
KEY POINTS
GLOSSARY
ACKNOWLEDGMENT
REFERENCES

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch47.

Electronic Health Records and Their Implications and Opportunities for Laboratories

Roger L. Bertholf

OBJECTIVES

To describe the basic components of electronic health record (EHR) systems

To summarize recent regulations aimed at increasing the use of EHRs, including the HITECH Act, meaningful-use criteria, and federal certification of EHR systems

To discuss potential laboratory concerns and regulatory issues associated with increased use of EHRs in physician practices

To list laboratory strategies for information management in the EHR era

Management of a system requires knowledge of the interrelationships between all of the components within the system and of everybody that works in it.

W. Edwards Deming

Clinical pathology has always been a data-intensive enterprise. In the clinical laboratory, specimens are received and converted into data that are used to guide diagnostic and therapeutic decisions. Decades ago, the laboratory converted from paper to digital storage of the data generated, and the laboratory information system (LIS) became an essential tool for managing laboratory data. Developers of LIS products gradually improved their capabilities by including interfaces to automated analytical instruments and bidirectional functionality so that, eventually, the entire process from entry of a laboratory order to the reported result was automated. Finally, the LIS was interfaced to an electronic health record (EHR; sometimes referred to as the electronic medical record [EMR]) that stored essentially all the information about a patient that previously was contained in a patient's physical chart or record. Although the capacity of the EHR is restricted only by its design, laboratory data are a prominent component of the EHR and may include interpretative, cautionary, regulatory, or other advice in addition to the numerical or qualitative laboratory results.

The Health Information Technology for Economic and Clinical Health (HITECH) Act (part of the American Recovery and Reinvestment Act) (1), which was passed by Congress in 2009, effectively mandated the conversion of

本书版权归John Wiley & Sons Inc.所有

paper medical records into electronic form. The Centers for Disease Control and Prevention (CDC) outlined five potential benefits of the healthcare data interoperability:

1. Improving quality, safety, and efficiency, and reducing health disparities
2. Engaging patients and families in their health management
3. Improving care coordination
4. Improving population and public health
5. Ensuring adequate privacy and security protection for personal health information

The success of the program in meeting these five goals has been debated (2), but the use of an EHR in the practice of medicine is now commonplace.

In a sense, the EHR descended from an older electronic resource, the hospital information system (HIS). HIS software was primarily designed to meet the administrative needs of the hospital, much as the LIS provides operational data to laboratory administrators, but medical data, including laboratory results, were often incorporated into the HIS database and could be accessed by healthcare providers through that resource. In contrast, the principal focus of the EHR is on the healthcare provider, as it provides a portal through which all pertinent information about the patient can be accessed (as a replacement for the patient's chart) and also has the ability to accept orders for medication, therapy, laboratory tests, etc., and even facilitate electronic communication with patients and other healthcare providers. Contemporary EHR systems also include portals for patients to access their medical records, schedule appointments, and communicate with their providers.

At the present time, EHRs have not replaced the LIS, which is still used for myriad administrative functions, such as monitoring laboratory turnaround times, documenting compliance with various regulatory requirements, tracking laboratory utilization, and workflow analysis. There are some LIS products that have been developed alongside EHR systems, to make integration of the two easier. However, since the primary interface with healthcare providers has now become the EHR, the laboratory has both the challenge and the opportunity to use the additional functionality provided by the EHR to optimize the effectiveness of that interaction as it pertains to laboratory utilization.

Electronic Health Records

Definition and Components

Fundamentally, the EHR is a repository of digitized medical information that may be considered the electronic equivalent of a patient's medical chart. Although simply digitizing medical records might achieve economies of storage and access, and potentially security, the advantages of an EHR reach far beyond that. In 2003, the Institute of Medicine (IOM) issued a landmark report that proposed eight core capabilities that an EHR should possess (3):

1. *Health information and data:* Having immediate access to key information—such as patients' diagnoses, allergies, lab test results, and medications—would improve caregivers' ability to make sound clinical decisions in a timely manner.
2. *Result management:* The ability for all providers participating in the care of a patient in multiple settings to quickly access new and past test results would increase patient safety and the effectiveness of care.
3. *Order management:* The ability to enter and store orders for prescriptions, tests, and other services in a computer-based system would enhance legibility, reduce duplication, and improve the speed with which orders are executed.
4. *Decision support:* Using reminders, prompts, and alerts, computerized decision support systems would help improve compliance with best clinical practices, ensure regular screenings and other preventive practices, identify possible drug interactions, and facilitate diagnoses and treatments.
5. *Electronic communication and connectivity:* Efficient, secure, and readily accessible communication among providers and patients would improve the continuity of care, increase the timeliness of diagnoses and treatments, and reduce the frequency of adverse events.
6. *Patient support:* Tools that give patients access to their health records, provide interactive patient education, and help them carry out home monitoring and self-testing would improve control of chronic conditions, such as diabetes.
7. *Administrative processes:* Computerized administrative tools, such as scheduling systems, would greatly improve hospitals' and clinics' efficiency and provide more timely service to patients.
8. *Reporting:* Electronic data storage that employs uniform data standards would enable healthcare organizations to respond more quickly to federal, state, and private reporting requirements, including those that support patient safety and disease surveillance.

The IOM report expresses the vision of an EHR that is central to essentially all patient care activities, giving providers a consolidated tool set that is capable of a wide array of functions that formerly required many independent resources. These resources include such things as the patient's chart, data analysis and graphing software, a

本书版权归John Wiley & Sons Inc.所有

prescription pad, test order forms, a separate email platform, and scheduling software, to name just a few. In addition, the EHR includes functions that were previously unavailable, such as patient access to medical records and decision support for healthcare providers.

The basic EHR functions that relate to laboratory services include test ordering and presentation of laboratory results, along with comments and interpretive advice that fall under the umbrella of "clinical decision support." The flexibility of EHR solutions creates opportunities to influence, and help optimize, the utilization of laboratory resources. Of particular interest is the capability to provide advice on the most appropriate laboratory tests to order in a specific clinical scenario. Laboratory tests that are clearly not indicated in certain situations may be suppressed, or useful laboratory studies suggested. These capabilities provide useful feedback to clinicians that should result in better and more cost-effective healthcare.

The EHR has been defined in federal legislation as well (42 U.S. Code § 300jj). The definition includes:

- Patient demographic and clinical health information, such as medical history and problem lists
- Clinical decision support
- Computerized provider order entry (CPOE)
- Capture and query of information relevant to healthcare quality
- The ability to exchange and integrate electronic health information with other sources

Status of EHR Use

Although federal incentives have resulted in widespread implementation of EHRs in hospital environments, use of health information technologies in primary care practices has lagged behind. In a survey reported in 2021, investigators found that while use of electronic resources was relatively common among primary care practices, the advanced functionality of an EHR was utilized in only 30 to 50% of the offices (4). However, data from the Office of the National Coordinator for Health Information Technology reveals that 78% of physicians' offices were using a certified EHR in 2021 (5).

Federal Regulations Related to EHRs and Their Implications for Laboratories

Beginning with the 2009 HITECH Act, which established the Office of the National Coordinator for Health Information Technology (ONC), and continuing with the 21st Century Cures Act, which was signed into law in 2016 and promoted interoperability between EHRs, to the Cures Act Final Rule, issued in 2021, which prohibits blocking patient access to any information in their EHR, implementation of EHRs has been primarily driven by federal law. The Centers for Medicare and Medicaid Services (CMS) and ONC developed and coordinated two programs: the Electronic Health Record Incentive Program and the Certification Criteria for Electronic Health Record Technology, which included meaningful-use standards. These two programs were part of the 2011 Medicare and Medicaid EHR Incentive Programs, which are now known as the Medicare Interoperability Program (see https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms [accessed 9 May 2022]). EHR certification criteria ensured that EHR technology had the functional capabilities sufficient to meet requirements for meaningful use of the EHR. The agencies issued the requirements for meaningful use of an EHR in 2011, and the three main components were:

1. Use of certified EHR in a meaningful manner (e.g., e-prescribing)
2. Use of certified EHR technology for electronic exchange of health information to improve quality of health care
3. Use of certified EHR technology to submit clinical quality measures and other such measures selected by the Secretary

Fifteen core objectives were specified for healthcare professionals, and 14 were listed for hospitals. The core objectives most relevant to laboratory services were CPOE and decision support rules. Overall, the meaningful-use criteria were all directed toward five key objectives, previously listed.

The CMS implemented meaningful-use objectives in three stages:

- Stage 1: Data capture and sharing (2011 to 2014)
- Stage 2: Advanced clinical processes (2014 to 2018)
- Stage 3: Improved outcomes (2017 to 2019 and beyond)

Functional and technical capabilities of the EHR were established for each stage of implementation, and providers were required to demonstrate compliance with each set of requirements to be eligible for financial incentives or to avoid penalties. Individual providers who met the requirements received up to $44,000 in incentives over 5 years in the Medicare program and $63,750 in the Medicaid program (if participating by 2012). Hospital-based healthcare practitioners were not eligible to receive individual incentive payments, but incentives to hospitals began with $2 million base payments and increased from there based on such factors as the number of acute care inpatient discharges and number of inpatient bed-days. In 2015, penalties were implemented for providers who had not demonstrated meaningful use of EHRs, beginning with a

本书版权归John Wiley & Sons Inc.所有

1% reduction in the Medicare physician fee schedule amount for professional services. The penalty increased to 2% in 2016 and to 3% for 2017 and each subsequent year.

Meaningful-Use Requirements Directly Relevant to Laboratories

Stage 2 of the meaningful-use requirements added two core objectives, including secure communications and tracking medications, and two patient access objectives, both related to patients' ability to view, download, and transmit their health information online. In addition, the stage 2 objectives required that more than 55% of all clinical laboratory tests whose results are in either a positive/negative or numerical format be incorporated in certified EHR technology as structured data. In this context, the term "structured" refers to the requirement that laboratory data reside in the EHR as discretely accessible elements, as opposed to, for example, a scanned image of a laboratory report. Another stage 2 objective required submission of laboratory data in electronic form to public health agencies, where such reporting was required. Finally, stage 2 required that at least 30% of laboratory test orders be placed by CPOE, which paved the way for direct electronic transmission of the orders to the LIS.

EHR Certification

In 2010, the ONC published the Final Rule: Health Information Technology (45 CFR Part 170): Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology. The rule established the functional and technical specifications for the EHR, including three standards related to data storage and exchange:

- Data formatting compliant with Health Level 7 (HL7) version 2.5.1
- Vocabulary standards for representing electronic health information, such as ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification), SNOMED-CT (systemized nomenclature of medicine—clinical terms), and LOINC (Logical Observation Identifier Names and Codes)
- Data security and encryption standards

These standards were followed in September 2012 by an ONC publication that updated EHR Standards and Certification Criteria, known as the 2014 edition. The document specified that interfaces between the EHR and LIS should comply with the Laboratory Results Interface (LRI) Implementation Guide, which provides specifications that include LOINC, HL7 v.2.5.1, and SNOMED-CT. A parallel ONC initiative was the Standards and Interoperability (S&I) Framework, which, among several other aims, provided specifications for the laboratory order and results interfaces (LOI and LRI, respectively), which were released in 2014. The 21st Century Cures Act was signed into law on 13 December 2016, and the Cures Act Interim Final Rule with comment period was published in May 2020, but due to the public health emergency announced in response to the coronavirus disease 2019 (COVID-19) pandemic, many of the original deadlines for certification were extended.

Certification Criteria and Standards Most Relevant to Laboratories

The EHR certification criteria required that laboratory test results be stored electronically in a structured database and displayed in a format that is simple to interpret. In addition, the laboratory data had to meet all of the requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) for a laboratory report. The CLIA '88 specifications for laboratory reports include:

- The name of the patient
- A medical record number or other unique identifier
- The name and address of the laboratory that performed the test
- The report date
- The name of the laboratory test that was performed
- The source of the specimen, when applicable
- The result of the laboratory test, including units of measurement for quantitative results
- Any reason why the test was not performed, if applicable (e.g., insufficient quantity, hemolysis, etc.)

Although the requirements include all of the CLIA '88-mandated elements of a laboratory report, there was no further advice with regard to the specific formatting of the test results, which left considerable latitude in the design of the laboratory portions of the EHR. As noted above, the term "structured" referring to data storage was slightly vague but was taken to mean that the various elements of a laboratory result (e.g., numerical result, units, reference range, normal/abnormal, etc.) are stored as individually identifiable elements in the EHR, so that formatting may be done on the back end and consistently across all laboratory results. The EHR also must link a laboratory test result to a laboratory order by a qualified healthcare provider. Two important requirements for laboratories were that HL7 v.2.5.1 was required for transmitting reportable laboratory results to public health agencies and that LOINC was required as the vocabulary standard. The ONC has indicated broader future requirements for use of these formatting and nomenclature standards in future revisions of the certification criteria, primarily in the form of new data classes and elements. For example, version 2 of the U.S. Core Data for Interoperability added "Diagnostic

本书版权归John Wiley & Sons Inc.所有

Imaging" as a new data class that included "Diagnostic Imaging Test" and "Diagnostic Imaging Report" as data elements.

EHR certification criteria also include the capability to transmit reportable laboratory results to public health agencies and support for CPOE. Other certification criteria, such as decision support rules based on laboratory results and patient access to clinical information, including laboratory results, online involve the laboratory in more tangential ways.

Concerns and Implications for Laboratories Related to Increased Use of EHR Systems

Potential Consequences

The integration of laboratory test ordering (CPOE) and reporting into EHR systems has enormous implications for clinical laboratory administration and management. The consequences may either benefit or compromise the accuracy and efficiency of laboratory information. Consider these potential consequences.

Benefits

- The accuracy of electronically transmitted data is more reliable.
- Data in the EHR are more easily and reliably corrected, when necessary, compared to hard-copy reports.
- Laboratory data may be presented in a format that reveals trends over time.
- There is greater flexibility for customizing the format of reported laboratory test results, including the addition of interpretation comments or other information related to clinical decision support.
- Best practice alerts (BPAs) can be incorporated into the CPOE process, such as suggesting a more useful substitute test, advice on the proper frequency of a particular test, recommending additional tests that can be used in conjunction with the ordered test to enhance the clinical utility, etc.

Challenges

- There is great risk of information overload.
- Use of programmed "order sets" has the potential to increase unnecessary testing and billing.
- The formatting of laboratory information may be inconsistent across various display devices (laptop computers, tablets, and smart phones), requiring extensive validation of new test builds to ensure that no critical information is lost or hidden.

Decades ago, when laboratory information systems were first connected to analytical instruments so that results could pass directly across the interface to populate the electronic database, the reliability of laboratory data improved dramatically from manual data entry processes. The same benefit is gained when the EHR is interfaced to the LIS. In a 2019 study, Mays and Mathias found a 3.7% error rate in manually entered point-of-care testing results, and over 14% of the errors had the potential to threaten patient safety (6). Clearly, electronic transmission of laboratory data is a vast improvement over manual entry.

Laboratory Reports

One problem with hard-copy laboratory reports is that, once they have been sent to the provider, the laboratory no longer has any control over what happens to them. They may get misfiled, lost, or improperly amended or otherwise fail to become part of the permanent record. When the laboratory results are stored electronically, they are permanent and mostly secure from alteration. If the laboratory needs to change a result, as sometimes happens when an error in the laboratory occurs, the report can easily be updated; this is not easily done with hard-copy reports, which may remain in the patient's record even after a corrected report has been issued. This comparison of hard-copy and electronic reports is slightly misleading, because when an electronic record is corrected, the original report usually remains in the record for legal reasons, but the existence of a corrected report can be made clear whenever the laboratory result is accessed. This precaution is not usually available in a system based on hard-copy reports.

A significant advantage of electronically stored laboratory results is that they can be presented with historical data that reveals trends over time. This can be done with hard-copy reports as well, but it requires time and effort to locate previous results and perhaps transcribe the results to a form that shows changes over time. Contemporary EHR systems have sophisticated capabilities for displaying laboratory data in tabular or graphical formats that facilitate interpretation of the test results.

Another enhancement that the EHR can provide for laboratory data is the capability to customize the report format to maximize the value of the information it contains. Paper reports are mostly static, although the final printed form may undergo some degree of customization at the LIS level. The EHR provides a richer environment for creating individualized presentations of laboratory data. Enhancements might include such things as links to relevant literature or practice pathways, and interpretative guidelines.

When laboratory orders are placed electronically (CPOE), there are also opportunities to provide advice on the appropriate tests to be ordered. Beginning over a decade ago, several laboratory professional organizations developed programs to promote laboratory stewardship, which focuses on efforts to ensure that laboratory resources

本书版权归John Wiley & Sons Inc.所有

are used appropriately, efficiently, and ultimately to the improvement of patient care. Laboratory stewardship was one of the planks in a 10-point "manifesto" proposed by Plebani et al. in 2019 (7). Physicians receive minimal education in laboratory medicine (8), and yet they routinely choose from hundreds, if not thousands, of laboratory tests to inform their diagnosis and treatment decisions. Guidance from clinical laboratory professionals can, in some cases, help steer physicians toward the most appropriate tests to order. Such advisories, or BPAs, can be linked to certain laboratory orders that are often used inappropriately. A well-known example is laboratory assessment of vitamin D status. The proper test in nearly all circumstances is that for 25-hydroxyvitamin D, the precursor of the active form of the vitamin, 1,25-dihydroxyvitamin D. Most laboratories offer both tests, but measuring the latter is rarely clinically indicated, and it is often ordered by mistake. BPAs can inform the physician of the appropriate test when the 1,25-dihydroxyvitamin D test is ordered. However, studies of the effectiveness of BPAs in CPOE have not produced consistent results (9).

"Order Set" Challenges

A hidden danger associated with EHR and CPOE is the creation of "order sets," which allow providers to order multiple laboratory tests with a single selection. Order sets are a common functionality included in EHR systems and are intended to save providers time when certain laboratory tests are typically ordered in a particular clinical scenario. As anyone who manages EHR databases will confirm, the feature is quite popular, and understandably so. However, over time, laboratory services evolve to add new tests that replace older, less useful tests, and managing the task of updating order sets when they include outdated laboratory tests, or tests that are no longer considered useful in a particular clinical scenario, quickly becomes unwieldy as the number of order sets grows beyond certain limits. It is quite possible that physicians recognize that the test is no longer useful but, for the sake of expediency, choose to ignore the results of that test rather than update the order set to exclude it. As a consequence, the EHR and CPOE tend to increase the frequency of unnecessary or inappropriate laboratory test orders.

Information Overload

Although the EHR provides many advantages and opportunities for improving the communication of laboratory information, it creates some challenges as well. Perhaps foremost among the pitfalls of electronic presentation of laboratory information is the potential for "information overload." Most physicians—particularly those in hospital and emergency medicine practice—function under circumstances that create pressure to make decisions quickly. While it may be tempting to load laboratory reports in the EHR with extensive interpretative advice, in many cases such reports will not be read simply because providers do not have the time. A delicate balance must be maintained between providing useful information, such as microbiology organism isolation/clinical relevance and antimicrobial susceptibility results/comments, and limiting its amount to maximize the likelihood that it will be utilized by providers. Even outside the hospital or emergency department environment, physicians review staggering amounts of laboratory data. One study of primary-care physicians in a large healthcare system revealed that they review, on average, 930 laboratory test results and 60 pathology or radiology reports per week (10).

Formatting Incompatibilities

A final challenge involving the presentation of laboratory information in the EHR relates to formatting incompatibilities between the LIS and EHR. The LIS is designed to meet the needs of the laboratory and presents data in a format that is most easily accessed for review. When the data are passed along to the EHR, however, some reformatting may occur, and translation into the EHR format may not maintain the overall integrity of the information. For this reason, any new test build has to be extensively validated to determine whether the results appear in the EHR without loss or substantial alteration of information. An example might be when important interpretative information added to a laboratory result in the LIS appears directly below the result but in the EHR is hidden within an appended file that can be read only by clicking on an icon or menu choice, making it far less likely to be viewed. User training is essential to ensure that providers know how to access important clinical information associated with any laboratory result and understand how critical the information may be to clinical care and patient safety.

While the EHR provides a flexible platform for transmitting laboratory test information to physicians, there is also potential for undesirable and potentially harmful ramifications when the fidelity of the information is compromised by poor translation from the LIS to the EHR. Some of these consequences can be anticipated, but others may not. A common example is the units in which concentrations are expressed. Some commonly used units include Greek letters (e.g., "μg" for "microgram") that may not be included among the alphanumeric characters in the EHR. This is particularly important for pharmacies, where a misinterpretation can result in a medication error. The laboratory uses a variety of abbreviations for units of mass, amount, and volume (mcg, μg, mg, mmol, μmol, nmol, mL, dL, L, etc.), and in a structured data format, these will be discrete elements that must be correctly matched with the numerical result of the test and displayed in a manner that is unambiguous. It is wise to engage the help of

本书版权归John Wiley & Sons Inc.所有

personnel trained in pathology informatics when considering the design and implementation of laboratory-related EHR information.

Results Management

Laboratory Report Components

CLIA '88 and laboratory accrediting agencies require that certain elements accompany any laboratory result displayed in a patient medical record, electronic or otherwise. A reference range must be specified, and the units in which quantitative results are expressed must be specified. In addition, it is customary to indicate whether a quantitative result is above or below the reference range; usually this is indicated by an "H" or "L," respectively. An EHR might also change the font or background color to indicate abnormal results. It is also common to indicate if a result exceeds a critical threshold, usually with the character "C." Finally, results that are not within the reportable limits for the analytical method are typically reported as ">[upper reportable limit]" or "<[lower reportable limit]," with the quantitative limits replacing the bracketed terms. Other information that ordinarily accompanies laboratory test results includes comments on specimen integrity (e.g., "hemolyzed"), notifications (e.g., name of person to whom a critical result was reported), and the name of the laboratory that performed the test. A list of variable elements of laboratory results to be displayed in an EHR appears in Table 47.1.

Laboratory Report Retrieval

Although the digital environment of an EHR offers many options for displaying laboratory data, it is customary to group tests into categories such as chemistry, microbiology, hematology, serology, etc. The choice of categories and which tests to include in them is flexible but not trivial, because the groupings that make sense to laboratorians might be confusing or counterintuitive to clinicians trying to locate an individual laboratory result. For example, laboratories typically segregate point-of-care testing data from the results obtained on the automated analyzers in the core laboratory. It makes sense to separate the two, because different technologies, operators, and laboratory accreditation standards (waived versus moderately complex) are involved.

Table 47.1 Laboratory report elements subject to variation in EHRs

Cumulative result display and format
Reference ranges
Abnormal result flags
Result comments and footnotes
Name and address of performing laboratory
Preliminary reports
Corrected reports

But a clinician seeking to access historical blood glucose data for a patient is unlikely to understand why the results are split between two locations in the EHR. Grouping of laboratory tests into categories, and their presentation in an outline format, requires careful consideration of the ways in which users of the EHR will attempt to access the information and their presumed understanding of the categories into which various laboratory tests fall.

Cumulative Laboratory Results

Presentation of cumulative laboratory results creates additional challenges, as space on a display screen is limited and therefore must be allocated judiciously. When limited space is allocated for laboratory results, frequent casualties include such things as reference ranges, comments, and interpretive advice. These elements, sometimes essential to the proper interpretation of laboratory results, may be concealed behind an ambiguous icon that has to be selected to view the information. As noted earlier, information requiring an extra step to access is less likely to be viewed than the information immediately displayed. A functional design of the laboratory result display requires a balance between the value of cumulative data and the need to provide all the essential information that accompanies a result without requiring cumbersome additional steps to access it. Optimization of the laboratory data format requires extensive testing and validation with experienced informaticians.

Laboratory Data Display Issues

Certain types of laboratory data can be particularly challenging to display in a concise digital format.

- Microbiology results often have narrative components, and antibiotic sensitivity studies can have quantitative and qualitative components.
- Transfusion medicine/blood bank tests for unusual antibodies can be quite complex and difficult to summarize succinctly.
- Molecular and genetic testing typically requires narrative interpretation.
- Serum protein or hemoglobin electrophoresis results are usually narrative.
- Therapeutic drug levels must be specified as peak, trough, or random.
- Serological results expressed as titers can easily be misinterpreted.
- Anatomic pathology reports may have elements of histochemistry mixed in with interpretive comments.

Validation of EHR Laboratory Report Displays

Laboratories have significant responsibilities in the validation of laboratory reports displayed in the EHR. The validation process must ensure not only that clinicians

本书版权归John Wiley & Sons Inc.所有

are given relevant laboratory data in a format that is easily accessed and interpreted but also that all of the applicable regulatory and accreditation requirements for laboratories are met. Questions to address during validation include the following.

- Are laboratory results presented accurately in the EHR?
- Are all required data elements present?
- Are results displayed in a manner that is potentially misleading to the clinician?

Physician Alerts

Along with a wide array of options for displaying laboratory data, an EHR also includes functionalities for alerting physicians when results meet certain criteria, such as critically high or low results, positive serological studies, antibiotic-resistant infections, and other scenarios that require urgent attention. These notification functions are customizable by user, location, laboratory, and of course individual test. However, since accreditation standards require that critical results be reported within a certain time limit (ordinarily, 30 minutes), laboratories must still call the provider to report any critical results so that the time can be documented.

When configuring notifications in the EHR, communication with users is essential to determine which notifications should be implemented. Just as the EHR has the potential for "information overload," so, too, it may create desensitization to important laboratory information if notifications occur too frequently and do not influence diagnostic or treatment decisions.

Laboratory Test Result Delivery in an Integrated Healthcare Network

A final complication in the display of laboratory test results in the EHR occurs when the EHR serves an integrated healthcare delivery network, which may include multiple hospitals, emergency care centers, outpatient clinics, assisted-living facilities, and even private physicians' offices. Any or all of these facilities may offer clinical laboratory services, even if they are limited to a handful of point-of-care tests. When laboratory data from multiple facilities populate the same EHR, there is great potential for users to be confused by differences in reference ranges, reportable limits, and other test-related parameters due to the specific methods used in the various laboratories. These differences create two problems: first, the same test must be configured for every individual laboratory performing it, and second, results from two laboratories often will not agree, and clinicians may wonder which is correct. The latter concern is particularly problematic for laboratory tests that are interpreted primarily based on changes over time rather than absolute values. An example is tumor markers, which clinicians follow to detect cancer recurrence but which are analytes that are, in many cases, poorly harmonized between different methods by which they are measured. It may be necessary to specify not only the laboratory where the test was performed but also the analytical method used to perform the test. Additionally, laboratories within the network may be using different LIS products, which multiplies the effort required to interface with the EHR.

For these reasons, there is great incentive for integrated healthcare systems sharing a common EHR to consolidate laboratory services where practical and, when multiple laboratories are in service, to standardize the analytical platforms and test methods to the greatest extent possible.

Computerized Provider Order Entry

Introduction

Prior to the COVID-19 epidemic, which altered normal healthcare spending in many ways, laboratory charges accounted for just under $8 billion of the $800 billion in total Medicare spending, or about 10% of healthcare costs. Despite this relatively low contribution to overall healthcare spending, laboratory utilization has been the focus of many initiatives to improve the efficiency and cost-effectiveness of healthcare. The "Choosing Wisely" campaign launched by the American Board of Internal Medicine is a good example of such an initiative, dedicated to ". . .helping patients choose care that is: 1) Supported by evidence, 2) Not duplicative of other tests or procedures already received, 3) Free from harm, and 4) truly necessary" (https://choosingwisely.org/) (accessed 9 May 2022). Among the partner organizations that support and contribute to the effort are several medical laboratory professional societies, including the American Society for Microbiology, the Association for the Advancement of Blood & Biotherapies (formerly the American Association of Blood Banks), and the American Society for Clinical Pathology. These professional laboratory organizations help define the parameters of responsible and cost-effective laboratory utilization.

Among the many features of the EHR that provide the laboratory with opportunities to influence utilization of laboratory resources, the CPOE is undoubtedly the most potent. Table 47.2 presents a list of CPOE-based methods to improve test utilization.

The impact of CPOE on medical care has been widely studied. Elshayib and Pawola (11) reviewed the literature on CPOE and medication errors, primarily focusing on the unintended consequences that the process creates. However, studies that examine the influence of CPOE on laboratory utilization have produced inconsistent results (12). Most studies show that CPOE interventions can reduce the number of laboratory tests ordered, but

本书版权归John Wiley & Sons Inc.所有

Table 47.2 CPOE-based methods to improve test utilization[a]

CPOE ordering templates and order sets
Alerts for redundant orders
Constraints on recurring orders
Display of previous laboratory results during ordering process
Integration of practice guidelines, care maps/care pathways
Corollary test recommendations
Display of test costs
Unbundling of test panels into individual components

[a] Modified from reference 20.

data on how the interventions affected patient care are sparse. Furthermore, the effects of the CPOE intervention on test ordering practices are often temporary. Randhawa et al. critically assessed the design of CPOE interfaces, providing suggestions to enhance their usability (13).

When evaluated with regard to the meaningful-use criteria that focus on laboratory orders placed in the EHR, studies have failed to establish a clear relationship between CPOE and patient safety, patient satisfaction, or cost per Medicare beneficiary (14).

CLIA '88 Required Laboratory Test Request Elements

For laboratories, an additional consideration is the elements of a laboratory test request that are required by CLIA. These include such things as identifying the person (or laboratory) ordering the test, the patient's name or unique identifier (such as medical record number), the age, sex, and date of birth of the patient, test name, specimen source (if appropriate), and the specimen collection time and date. Some anatomic pathology tests may require additional information, such as the date of the patient's last menstrual period for Pap smears, or relevant clinical and historic information. Microbiology tests often require additional information to ensure that the proper laboratory procedure is performed (15). The CPOE design must incorporate the capability to provide these elements to comply with CLIA requirements for laboratory test orders. For this reason, input from laboratory management and directors is essential when designing CPOE systems.

Appropriate Choice of Individual Laboratory Test Names

Another aspect of good CPOE design is the appropriate choice of names for individual laboratory tests, to avoid confusion or misinterpretation by clinicians ordering the tests. Many tests can have similar-sounding names, such as the previously cited example of vitamin D metabolites. "LIP" may refer to lipase, lipoprotein, or lipid panel. "BNP," for "brain-type natriuretic peptide," is easily confused with "BMP," for "basic metabolic profile." BUN (blood urea nitrogen) and urea refer to the same waste product of protein catabolism, but the former is customarily used in the United States, whereas most of the rest of the world recognizes the latter. Consideration should also be given to the search engine used in CPOE to find a particular test, and common synonyms for laboratory test names should be included to maximize the chance that a search will produce the correct test. Selection and harmonization of test codes was among the "top 10 challenges encountered when implementing an interfaced EHR-LIS" cited by Petrides et al. (16)

In a review of 24 published reports of various decision support strategies deployed in primary care CPOE systems to improve laboratory utilization, Lillo et al. (17) found that interventions included:

- Educational strategies intended to inform providers of the proper use of certain laboratory tests
- Displaying the cost of ordered laboratory tests
- Providing feedback to providers on laboratory test ordering patterns
- Administrative changes, such as removing tests from the CPOE menu or reconfiguring panels of laboratory tests
- "Soft blocking," which requires extra steps to proceed beyond pop-up windows
- "Hard blocking," which involves rejecting test orders under certain circumstances

Some interventions involved combinations of two or more of these strategies. The authors of this review (17) found that use of these strategies, while generally reducing the number of laboratory test requests, did not reveal a consistent pattern, perhaps because the number of permutations was too large to make direct comparisons. Although use of the CPOE to improve laboratory utilization is a promising feature of the EHR, and many institutions have implemented decision support elements in their CPOE, data on the most effective strategies seem to be lacking.

When choosing a name for a laboratory test, it is also important to consider the billing code that will be associated with it. Insurance company employees who review hospital bills are likely to have limited knowledge of laboratory test terminology and to deny a payment for a laboratory test that does not match the description of the code under which it is billed. Substantial agreement with the LOINC associated with the particular test is also desirable, to avoid confusion about whether the test has been correctly coded.

EHR-LIS Interfaces

The EHR communicates with the LIS through an interface in the same way that automated clinical analyzers transmit results to the LIS. A complete discussion of the specific

本书版权归John Wiley & Sons Inc.所有

design elements that comprise a computer interface is beyond the scope of this chapter, but certain features that influence how the laboratory interacts with the EHR to seamlessly receive test orders from providers and transmit results back to them are discussed here.

The federal meaningful-use requirements increased the demand for LIS interfaces with various EHR products in use by healthcare facilities and private physician practices. Connectivity to "foreign" computer networks is an overarching security concern for information technology (IT) professionals, and the design of the interface must address both the integrity of transmitted data and the security of the respective networks in which the LIS and EHR reside. In most healthcare facilities, both the LIS and the EHR exist within a single network that is managed by the IT staff. However, interfaces with external EHR products present many challenges that go beyond the basic design to accommodate the exchange of data. Will the EHR provide a "back door" for hackers to access the LIS? Does the EHR have sufficient user identification to ensure that Health Insurance Portability and Accountability Act (HIPAA) privacy requirements are met? Who is responsible for the technical support and maintenance of the interface? Since the providers interact only with the EHR, they are likely to view it as the primary data repository for the laboratory, when in fact it is a secondary repository—the LIS is primary—and the integrity of the laboratory data in the EHR relies on the interface. A potential consequence of this perception is that when an error occurs in the interface, it will be viewed as a laboratory error even though it might have been completely out of the laboratory's control. Validation of the interface must include the input of laboratory personnel to simulate all conceivable scenarios to ensure that the interface correctly transmits information from the LIS to the EHR.

To simplify the task of interfacing the LIS to, potentially, multiple EHRs, an interface engine may be used. An interface engine is software designed to facilitate communication between computer systems or networks. For healthcare systems, the interface engine Health Level Seven (HL7) was created.

Technical Aspects of Interfaces: HL7 and LOINC

Founded in 1987, Health Level Seven International, Inc., is a nonprofit organization that created the specifications for interoperability between healthcare data systems; these specifications are known as the HL7 standards. Despite the existence of these standards, true interoperability of healthcare data systems has proved to be an elusive goal (18). There are a variety of factors that probably contribute to the slow progress, among them a hesitancy on the part of healthcare providers to share information with other providers, whom they may regard as competitors. Note that "interface" and "interoperability" are not synonymous terms: the former is the programming code that allows computers to exchange data, whereas the latter refers to the form and function of the shared information. Interoperability requires an interface, but the interface itself does not facilitate interoperability unless information is shared in a format that is functionally accessible to the system that receives the data. In semantic interoperability, which is the most sophisticated form of interoperability, the host system receives and uses data as though they had originated there (19).

Due to the complexity of healthcare information, a functional EHR requires definition beyond the rudimentary specifications of HL7. In 2012, work began on developing the Fast Healthcare Interoperability Resources (FHIR) to meet this need. FHIR included an extensive set of standards for information exchange between healthcare systems that were free and designed to be easily implemented (even turnkey is some settings). The standard was supported by most EHR vendors and was based on widely accepted web standards such as XML, JSON, HTTP, and OAuth. FHIR also included a large set of tools available online for designing and customizing data exchange systems.

More pertinent to the exchange of laboratory information are the standards that exist for identifying specific laboratory tests. LOINC is a data standard that defines a set of universal codes for identifying laboratory tests (and other clinical observations). More than 30,000 LOINC codes have been defined. The LOINC standards enable exchange and comparison of laboratory data across different information systems. The LOINC codes have been adopted by the ONC as part of its specifications. One of the primary advantages of LOINC was elimination of the need for large translation tables, which used to be a standard feature of LIS-EHR interfaces.

Operational Challenges for Laboratories with LIS-EHR Interfaces

CLIA regulations place a responsibility on the laboratory to ensure accurate transmission of laboratory results in interfaces:

> 42 CFR 493.1291(a) *The laboratory must have adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:*
> 1. *Results reported from calculated data.*
> 2. *Results and patient-specific data electronically reported to network or interfaced systems.*
> 3. *Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.*

本书版权归John Wiley & Sons Inc.所有

Table 47.3 Operational considerations in LIS-EHR interfaces

Maintenance of EHR settings related to laboratory tests
Change control and communication (e.g., test definition updates)
Troubleshooting and client support
Training of EHR users in test result viewing and (eventually) test ordering
Handling of corrected results
Monitoring or quality of service
Client site contact and engagement

Consequently, clinical laboratories must have access to technical personnel qualified to manage computer resources including interfaces with external EHRs. In the case of larger clinical laboratories, the IT personnel may be employees of the laboratory itself, whereas smaller facilities may have IT support for the entire institution, including the laboratory. Whatever the administrative structure, it is essential for the laboratory to have the ability to establish, modify, test, and monitor the interface to ensure that test results are being correctly transmitted and displayed in the EHR. This requirement can present challenges when the EHR is managed by a different entity, because the laboratory must be made aware of any changes to the EHR that may affect laboratory test results, including the way they are displayed. For example, critical advice that the laboratory may issue along with a laboratory test result, such as "Specimen was slightly hemolyzed," may be hidden from view in the EHR and accessible only by clicking on an icon, making it unlikely to be read. These challenges may be even greater when commentary included in clinical laboratory and anatomic pathology reports is transmitted. Mechanisms must also be in place to facilitate feedback from EHR users to the laboratory, either directly or through their own IT support staff.

Table 47.3 lists several operational considerations in LIS-EHR interfaces.

Tactics for Working with EHR Support Staff

In the hospital environment, IT support staff are typically shared among many departments, and the implementation of an EHR is therefore coordinated with LIS support. It is common to have several IT staff dedicated to laboratory issues. In a community or referral laboratory environment, however, the LIS and EHR may be under separate administrative control, and communication will be essential to maintain the proper function of both. The communication structure must be able to accommodate urgent demands, because failure of the EHR to properly receive and display laboratory results can have implications for patient safety. As anyone who works in a clinical laboratory knows, most problems that occur require immediate attention, and one of the most devastating problems that can occur is failure of the computer systems that handle laboratory results. LIS or EHR failure will force the activation of "downtime procedures," which inevitably include manual processing of test results. In a busy clinical laboratory, downtime procedures can quickly overwhelm staff and resources. Therefore, IT support staff always need to be available to address unanticipated system downtimes. Other issues requiring attention of IT support staff include changes in test methodology that affect reference ranges, reagent recalls that may invalidate previously verified results and necessitate corrections in the EHR, and the need to notify providers of important changes in the appropriate use and/or interpretation of laboratory tests.

A good working relationship between the laboratory and the IT staff responsible for EHR support can be key to addressing EHR-laboratory information management issues. The EHR analysts (or IT support staff) create the EHR definitions and configurations that users experience directly. The IT staff are also responsible for EHR testing and validation. Whether the laboratory or the IT support staff initiates the establishment of a communication network to address the unique aspects of EHR function that influence laboratory data, its existence is essential for the safe and reliable transmission of test results from the LIS to the EHR.

The importance of communication between the laboratory and IT support staff cannot be overemphasized. The principal currency of the laboratory's value to a healthcare institution is data, and a modern clinical laboratory relies heavily on computer systems to manage those data. The LIS and EHR are the input and output, respectively, vehicles for laboratory data, and their function is critical to the hospital and external clients the laboratory serves. Without dedicated IT personnel to promptly address issues related to the LIS and EHR, the entire system is at risk of failure.

Laboratory Involvement in EHR Selection and Implementation

Implementation of an EHR is a costly venture for hospitals, clinics, and private physician offices. As a result of the incentives created by the HITECH Act (discussed above), most large healthcare facilities have already migrated to an EHR. However, many private physician offices have not yet adopted an EHR, and there may be some hospitals still in the process of selecting or implementing an EHR. In those cases, it will be very beneficial for the laboratory to participate in the process of selection and implementation, because laboratory results will ultimately be a significant part of the EHR and selecting a product that is known or designed to be compatible with the LIS will greatly simplify the implementation.

Selection and implementation of a new EHR provide many opportunities for the laboratory to increase its

本书版权归John Wiley & Sons Inc.所有

interactions with IT staff. Ideally, the laboratory should participate actively in selecting the EHR product. A study group for selecting an EHR should consist of representatives from IT, pathology, the laboratory, pharmacy, radiology, and various clinical departments. Laboratory representation ought to include the laboratory medical and administrative directors along with managerial and supervisory personnel. Although the contributions of the laboratory to the EHR selection process may vary, at a minimum, the laboratory should attend EHR vendor demonstrations and provide evaluations.

Once a new EHR has been selected, the laboratory will have important roles in its implementation. As in the selection process, the institution will likely convene committees and work groups in which the laboratory should expect to have formal representation. Implementation teams typically work through the configurations and definitions in the EHR system that will underpin the clinical workflow and documentation. Key areas for laboratory input include the configuration of provider laboratory test order entry (CPOE) processes and the ways laboratory results are managed and displayed. A particular area, for instance, in which the laboratory can provide valuable input is the design of the structure and display of screens for cumulative display (by date) of laboratory results, in particular, how tests are grouped logically by discipline (e.g., chemistry, hematology, etc.). The implementation phase is when the laboratory can work with the EHR implementation team to establish processes for change control and communication for changes in laboratory test definitions or addition of new tests. In this phase of implementation, it is necessary to ensure correct mapping and data exchange between the LIS and EHR.

SUMMARY

In 2009, the HITECH Act created incentives for healthcare providers to implement EHRs. Over the ensuing decade, the ONC created standards for EHR implementation, including meaningful-use criteria to demonstrate that the EHR was fulfilling its promise to improve the quality and cost-effectiveness of healthcare in the United States. These federal programs have had a profound influence on the way health information is recorded, stored, and accessed. Laboratory data are some of the most important elements of healthcare, so the laboratory is one of the primary stakeholders in any implementation of an EHR. In addition, the laboratory has several statutory responsibilities under CLIA for ensuring the integrity of electronically transmitted laboratory results, which makes laboratory involvement in the selection and implementation of an EHR essential.

The EHR provides many opportunities for the laboratory to improve the process of ordering and interpreting laboratory tests. CPOE creates a means by which the laboratory can influence the choice of a laboratory test by advisory prompts triggered under appropriate circumstances. Digital storage of laboratory results allows display of historical and current results, often in graphical format to reveal trends.

A close coordination between network and computer system (IT) support personnel and the laboratory is necessary to ensure the proper function of the EHR, based on the design of the interface between the EHR and the LIS.

KEY POINTS

- Federal regulations and programs aimed at driving more widespread use of EHRs have defined criteria for meaningful use of "certified" EHRs that eligible healthcare providers and hospitals must meet to qualify for financial incentives and to avoid future penalties.
- The components of an EHR most relevant to the laboratory are test result management, CPOE, and the interface between the LIS and EHR.
- As EHR use by hospitals and provider practices expands, laboratories can expect to see greater expectations for electronic exchange of laboratory data and LIS-EHR interfaces.
- Deployment and ongoing support of LIS-EHR interfaces require attention to technical, operational, and financial considerations.
- Although the laboratory may lack direct control over the EHR system, the laboratory possesses the domain expertise to contribute to the optimal handling of laboratory information in the EHR.
- Laboratories must develop organizational approaches and allocate resources toward influencing EHR-related issues in their institutions.

GLOSSARY

Best practice alert A piece of information prompted by a certain test order that provides evidence-based advice that may affect the laboratory order and improve the clinical information obtained from a laboratory test result.

Centers for Medicare and Medicaid Services (CMS) Federal agency that administers the Medicare and Medicaid national health insurance programs.

Certified EHR EHR (single or combination of EHR modules) that has been tested and as having met all applicable ONC certification criteria.

Computerized provider (or physician) order entry (CPOE) EHR feature that allows healthcare providers to enter

本书版权归John Wiley & Sons Inc.所有

orders such as laboratory test orders or medication orders electronically.

EHR module System that meets at least one of the ONC EHR certification criteria and can be tested and certified in accordance with the ONC EHR certification program; combinations of EHR modules can be used to meet the definition of certified EHR technology.

Electronic health record (EHR) Sometimes called the electronic medical record (EMR), a longitudinal, computerized collection of health information related to an individual's health and healthcare with functions such as CPOE, decision support, and capabilities for electronic exchange of health information.

Health Information Technology Economic and Clinical Health (HITECH) Act 2009 federal law intended to promote the use of interoperable health information technology and electronic health records.

Health Level Seven (HL7) Widely used standard for electronic data exchange in healthcare that specifies format and syntax for data messages in system interfaces.

HTTP (Hypertext Transfer Protocol) Application-layer protocol for transmitting hypermedia documents such as HTML (Hypertext Markup Language), used in most web documents.

Interface Software and connections that translate electronic messages so different computer systems can exchange information.

Interface engine Software that translates and routes electronic messages among multiple systems, reducing the number of individual interfaces needed for multiple systems.

International Classification of Diseases (ICD) Health data standard included in the World Health Organization Constitution and Nomenclature Regulations.

Interoperability In the context of computer networks, the ability of computer systems or software to exchange and make use of information.

JSON (JavaScript Object Notation) Data interchange format.

Laboratory information system (LIS) Interrelated software programs and hardware that provide electronic data processing and information management functions necessary to support laboratory operations.

Laboratory test formulary List or menu of laboratory tests that are approved and available for ordering by providers in a healthcare organization.

LIS dictionary LIS database table that stores data definitions that determine conventions, names, formats, and rules for information processing in the laboratory.

LOINC (Logical Observation Identifier Names and Codes) Data standard that defines a set of universal codes for identifying laboratory tests (and other clinical observations) in computer systems, intended to enable exchange and comparison of data across different information systems.

Meaningful-use criteria A set of criteria established by the CMS as part of the Electronic Health Record Incentive Program, referring to the use of certified EHR technology to meet specific objectives defined in the regulation.

OAuth (Open Authentication) Open standard that specifies how computers can access data on other computers.

Office of the National Coordinator for Health Information Technology (ONC) Federal agency in the Department of Health and Human Services in charge of national efforts to advance the use of health information technology.

Standard In the context of information systems, a set of agreed-upon rules, specifications, and/or conventions that govern the design and function of information systems, with the idea that systems that adhere to a given standard will be compatible with other systems that adhere to the same standard.

Structured data Data stored in an electronic database in discretely accessible elements (e.g., "concentration," "units," "reference range," etc.).

SNOMED-CT (Systemized Nomenclature of Medicine—Clinical Terms) A set of medical terminology standards developed and published by SNOMED International.

XML (Extensible Markup Language) Standard markup programming language that defines rules for encoding data.

ACKNOWLEDGMENT

This chapter is an updated version of a chapter by Walter H. Henricks that appeared in the 2nd edition of this book.

REFERENCES

1. **Steinbrook R.** 2009. Health care and the American Recovery and Reinvestment Act. *N Engl J Med* **360**:1057–1060.

2 **Himmelstein DU, Wright A, Woolhandler S.** 2010. Hospital computing and the costs and quality of care: a national study. *Am J Med* **123**:40–46.

3. **Committee on Data Standards for Patient Safety, Board on Health Care Services, Institute of Medicine.** 2003. *Key Capabilities of an Electronic Health Record System: Letter Report*. National Academies Press, Washington, DC.

4. **Cross DA, Stevens MA, Spivack SB, Murray GF, Rodriguez HP, Lewis VA.** 2022. Survey of information exchange and advanced use of other health information technology in primary care settings: capabilities in and outside of the safety net. *Med Care* **60**:140–148.

5. **Office of the National Coordinator for Health Information Technology.** 2023. Office-based physician electronic health record adoption. Health IT Quick-Stat #50. https://www.healthit.gov/data/quickstats/office-based-physician-electronic-health-record-adoption. Accessed 4 August 2023.

6. **Mays JA, Mathias PC.** 2019. Measuring the rate of manual transcription error in outpatient point-of-care testing. *J Am Med Inform Assoc* **26**:269–272.

7. **Plebani M, Laposata M, Lippi G.** 2019. Driving the route of laboratory medicine: a manifesto for the future. *Intern Emerg Med* **14**:337–340.

本书版权归John Wiley & Sons Inc.所有

8. Molinaro RJ, Winkler AM, Kraft CS, Fantz CR, Stowell SR, Ritchie JC, Koch DD, Heron S, Liebzeit J, Santen SA, Guarner J. 2012. Teaching laboratory medicine to medical students: implementation and evaluation. *Arch Pathol Lab Med* **136**:1423–1429.

9. Rubinstein M, Hirsch R, Bandyopadhyay K, Madison B, Taylor T, Ranne A, Linville M, Donaldson K, Lacbawan F, Cornish N. 2018. Effectiveness of practices to support appropriate laboratory test utilization: a laboratory medicine best practices systematic review and meta-analysis. *Am J Clin Pathol* **149**:197–221.

10. Poon EG, Wang SJ, Gandhi TK, Bates DW, Kuperman GJ. 2003. Design and implementation of a comprehensive outpatient Results Manager. *J Biomed Inform* **36**:80–91.

11. Elshayib M, Pawola L. 2020. Computerized provider order entry-related medication errors among hospitalized patients: an integrative review. *Health Informatics J* **26**:2834–2859.

12. Bindraban RS, Ten Berg MJ, Naaktgeboren CA, Kramer MHH, Van Solinge WW, Nanayakkara PWB. 2018. Reducing test utilization in hospital settings: a narrative review. *Ann Lab Med* **38**:402–412.

13. Randhawa GK, Garnett A, Huang S, Dhot P, Fyfe ML. 2019. Evidence-based usability principles for safe computerized provider order entry (CPOE) interface design. *Stud Health Technol Inform* **264**:1947–1948.

14. Murphy ZR, Wang J, Boland MV. 2020. Association of electronic health record use above meaningful use thresholds with hospital quality and safety outcomes. *JAMA Netw Open* **3**:e2012529.

15. Georgiou A, Prgomet M, Toouli G, Callen J, Westbrook J. 2011. What do physicians tell laboratories when requesting tests? A multi-method examination of information supplied to the microbiology laboratory before and after the introduction of electronic ordering. *Int J Med Inform* **80**:646–654.

16. Petrides AK, Tanasijevic MJ, Goonan EM, Landman AB, Kantartjis M, Bates DW, Melanson SEF. 2017. Top ten challenges when interfacing a laboratory information system to an electronic health record: experience at a large academic medical center. *Int J Med Inform* **106**:9–16.

17. Lillo S, Larsen TR, Pennerup L, Antonsen S. 2021. The impact of interventions applied in primary care to optimize the use of laboratory tests: a systematic review. *Clin Chem Lab Med* **59**:1336–1352.

18. Braunstein ML. 2018. Health care in the age of interoperability: the potential and challenges. *IEEE Pulse* **9**:34–36.

19. Braunstein ML. 2018. Healthcare in the age of interoperability: the promise of fast healthcare interoperability resources. *IEEE Pulse* **9**:24–27.

20. Baron JM, Dighe AS. 2011. Computerized provider order entry in the clinical laboratory. *J Pathol Inform* **2**:35.

本书版权归John Wiley & Sons Inc.所有

48

Introduction
Hematology
Automated Enumeration of Cell Populations • Molecular Testing
Chemistry
Advances • Laboratory Computerization • Laboratory Automation
Microbiology
Advances • Microorganism Identification • Molecular Microbiology
Blood Transfusion and Coagulation
Coagulation and Thromboelastography • Inventory Tracking and Use
Point-of-Care Testing
Computerization • Rapid Assays • Developments during COVID-19
Molecular Diagnostics
Real-Time PCR
Outlook for the Future
Driving Forces • Device Miniaturization
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES

Current Trends in Instrumentation and Technology: A Look toward the Future

Patrick B. Kyle and Lauren McVoy

OBJECTIVES

To provide an overview of current trends in instrumentation and technology in the clinical laboratory (hematology, chemistry, microbiology, blood transfusion/coagulation, point-of-care testing, and molecular diagnostics)

To provide perspectives on how recent developments and other technologies are and will be shaping the laboratory

Innovation and renewal are required to keep a laboratory on the frontiers of science.

Burton Richter, Nobel Prize in Physics, 1976

THIS CHAPTER DISCUSSES ADVANCES IN INSTRUMENTATION and technologies in the clinical laboratory. While the evolution of the clinical laboratory has been a fascinating journey, the past 20 years have included significant advances in analytical techniques, assay refinement, instrument development, computerization, and automation. Manufacturers have developed not only instruments that are bigger and faster but also those that accommodate multiple detection techniques, perform wider varieties of tests, and are electronically interfaced to the laboratory information system (LIS). This chapter focuses on the current trends and latest advancements, as well as innovative technologies developed for incorporation into the clinical testing arena. Before addressing the current trends in each laboratory discipline, it is appropriate to discuss the organization and layout of the clinical laboratory. Laboratories are quite diverse and range from single-room clinic or physician office laboratories operated by one or two technologists to large reference laboratories or academic medical center laboratories that involve hundreds of employees comprising phlebotomists, couriers, technicians, technologists, information technology (IT) specialists, doctorate-level scientists, pathologists, and administrators. Therefore, one must recognize that any discussion of current laboratory trends and technologies will likely not apply to every laboratory. The most common type of clinical laboratory is likely one associated with a private hospital involving only the core disciplines. These typically include chemistry, hematology, microbiology, blood transfusion/coagulation,

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch48.

本书版权归John Wiley & Sons Inc.所有

and point-of-care testing. Larger laboratories may also include special chemistry, virology, cytology, cytogenetics, toxicology, endocrinology, flow cytometry, and molecular diagnostics and even subdivisions of these, such as molecular microbiology, molecular hematology, and others. Given that the larger laboratories span multiple rooms and may involve multiple buildings, these laboratories may put forth a great deal of effort to ensure efficient specimen processing, routing, and transportation. Efficient laboratory designs often include large open spaces, lean processing, and linear specimen flow to promote continuous rather than batch processing (1). Large laboratories may opt to include pneumatic tube distribution systems as well as robots and/or conveyor belt-type automation systems in order to achieve higher efficiency and throughput goals.

No discussion of the clinical laboratory would be complete without addressing laboratory automation. Automation is one of the most important breakthroughs in laboratory medicine in the past several decades (2). Discussions of total laboratory automation (TLA) have been in vogue for a number of years. The concept of TLA was introduced in 1989 by Masahide Sasaki at the Kochi Medical School in Kochi, Japan (3), in which a system of conveyor belts was used to transport laboratory specimens that were loaded onto the system by robotic arms. Current automation systems may be composed of many different modules to accommodate specimen accessioning, sorting, centrifugation, uncapping, aliquoting, labelling, recapping, incubating, routing, storage, and retrieval. A manufacturer may recommend a design or multiple combinations of modular components in order to satisfy a given laboratory's needs, goals, and test volume. Comparatively few laboratories have implemented TLA due to the high initial costs and the inherent complexities of diverse specimen types and specimen containers. However, thousands of laboratories have implemented some level of automation, whether for preanalytical specimen sorting or for the automation of specific laboratory sections (4). One simple but efficient step toward automation involves the implementation of an automated sample sorter module. After laboratory personnel deposit specimens into the module's hopper, a conveyor belt lift system transports each specimen past a barcode reader for accessioning. A robotic arm then transfers the specimens into appropriate racks designated for specific laboratory sections as defined by the tests that are ordered. Although a simple design, this system is possible only due to advances in computerization. Technologists tend to appreciate automation systems because they reduce or eliminate repetitive manual tasks.

There can be a significant cost associated with the implementation of large automation systems. These costs can be offset however by a reduction in the number of full-time equivalents (FTEs) required by the laboratory. Simply put, the use of laboratory robotics to perform manual repetitive tasks allows the laboratory to reallocate personnel to perform more technical tasks. This can be an important consideration when labor cost is one of the largest expenses in the laboratory. Another option to decrease automation and/or instrument cost would involve entering into a group purchasing organization (GPO). GPOs involve an agreement among multiple institutions to purchase common items from specific vendors. GPOs negotiate reduced costs due to the volume of products consumed by these groups. One caveat to this is that a given GPO may include only limited types of instruments or few automation choices. Every laboratory should make a comprehensive evaluation of its needs and the options available before making a decision. Automation systems are not perfect, and increased system complexity should be expected. Automation systems that boast postanalytical refrigerated specimen storage (sample farms) are advantageous in that specimens may be automatically retrieved and reintroduced into the instrument for reanalysis or for add-on tests (5). However, large amounts of floor space may be required, and analyte stability should be determined if long storage periods are anticipated (5). Benefits of laboratory automation include increased throughput, process standardization, improved specimen tracking, and decreased exposure of personnel to biohazards. In addition to the up-front cost of automation, challenges may include increased expenditures for consumables, heat generation, HVAC (heating, ventilation, and air conditioning) demand, electrical consumption, laboratory crowding, and decreased staff expertise in specific techniques (2).

Recent advances in computerization have profoundly revolutionized the clinical laboratory. Digital interfaces now allow the connection of laboratory instruments to the LIS for data transfer. An interface is a piece of computer hardware that is programmed to convert an instrument's data language to that of the LIS and vice versa. Initially, instrument-LIS interfacing was unidirectional, in that an analyst programmed the instrument with the patient ID, the test to be performed, and the specimen location. After analysis, the test results were electronically transmitted from the instrument to the LIS. Unidirectional interfacing has been replaced by bidirectional communication, in which the instrument queries the LIS about a bar code-labeled specimen, performs the requested tests, and transmits the results to the LIS. The incorporation of bidirectional interfacing not only has improved laboratory turnaround times (TATs) but also has dramatically reduced clerical errors associated with manual result entry (6, 7). The international standardization of the Health Level Seven (HL7) data transfer protocol allows hospital laboratories to interface their LIS with their chosen reference laboratories. The reference laboratory data are transferred

本书版权归John Wiley & Sons Inc.所有

automatically to the hospital laboratory LIS nearly as fast as they are acquired. As a result, reference laboratory interfacing has significantly reduced the number of technologists or data entry personnel required by the laboratory. The standardized data transfer protocol also allows laboratories to interface their LIS with their local health department for automatic transfer of reportable disease results.

Functionality within LIS systems has also evolved significantly. These utilities are observed throughout the clinical laboratory, where the LIS may be used to generate phlebotomy collection lists, reports for personnel productivity, monthly test volumes, physician orders, TATs, and others, as listed in Table 48.1. Instrument interfacing allows LIS-directed analysis of single analytes and comprehensive panels as well as reflexive testing. Given interfaced instruments and automatic result transfer, many laboratories also use the LIS to maintain quality control (QC) result data for each laboratory test. The LIS may also be programmed with QC accept/reject criteria to automatically alert the technologist that QC has failed. The LIS may also be programmed for automatic test result verification (also called autoverification), which prevents the manual review of test results. Criteria for autoverification are laboratory specific, but it usually proceeds as long as the result is not in a critical range and there are no (i) instrument errors, (ii) delta checks, or (iii) QC flags. Result autoverification has been shown to significantly reduce the TAT for test results (8). Laboratories may also notice decreased TATs for results that were not autoverified, because technologists can address the problem specimens in a more timely manner. One disadvantage of autoverification is the removal of human review, which may reveal trends in instrument data. For example, an error with a sodium assay that suddenly resulted in all values being reported with a significant positive or negative bias would likely be noticed by a technologist but might be autoverified depending on the programming scheme. Therefore, critical and life-threatening results should not be autoverified due to requirements that they be communicated to an appropriate healthcare provider. Most laboratories require documentation of the communication as well as accurate read-back of the results by the provider. However, even this burden can be reduced by electronic reporting, as some LIS systems can deliver critical results via instant messaging. These systems can also document the dates and times when the message was sent, received, and read. Given that the laboratory of a 500-bed hospital may make several thousand telephone calls for critical values each month, this function alone can remove an enormous burden from the laboratory.

Table 48.1 Common functions of laboratory information systems

Category	Functions
Preanalytical	Test requisition Phlebotomy collection lists Printing of specimen labels Specimen aliquot labels Specimen receipt Specimen tracking Listing outstanding specimens
Analytical	Document quality control Quality control error checks Generation of instrument worklists Instrument communication Calculation of results with formulae
Postanalytical	Result release Result inquiry Result receipt (from reference laboratory) Result review Manual result entry Automated result entry Result transmission (to CDC or other entity) Manual result verification Automated result verification Result delta checking Critical result alerts
Managerial	Determination of test volumes Reagent inventory tracking Tests per technologist Turnaround times Tabulation of billing totals

Forces outside the laboratory have also worked to increase the functionality of the LIS and hospital information system (HIS). In 2011 the Centers for Medicaid and Medicare Services (CMS) established the Medicaid and Medicare EHR incentives program (9) to encourage clinical providers, hospitals, and clinics to adopt certified electronic health record technology (CEHRT). The U.S. government sought to develop a single unified patient database that could be used by clinical providers, insurance companies, and the patients themselves. Stated goals included improving quality, safety, efficiency, and healthcare coordination as well as engaging patients in their health and ensuring adequate privacy and security for personal healthcare information. The U.S. government provided significant financial incentives for providers and hospitals to make changes in their IT infrastructure, with the goal of every eligible entity using an interoperable EHR by the year 2018. In 2015, the CMS established a final rule with the focus of improving patient care and outcomes with the use of CEHRT. Complete EHR interoperability had not been achieved by 2018, and in June 2018, the U.S. Food and Drug Administration (FDA) published a federal guidance document for the recommendations of using Logical Observation Identifiers Names and Codes (LOINC) (10). In this, the FDA encouraged the adoption of a consensus standard for laboratory test codes with the understanding that a consistent standard is required for a unified EHR. Since test results are a significant part of an

本书版权归John Wiley & Sons Inc.所有

electronic medical record, the FDA's guidance document provided a strong nudge toward EHR interoperability, which the healthcare industry is still working toward. Despite the enormity of revamping the nation's healthcare record system, significant advancements have been made, with over 70% of acute-care hospitals integrating data into the EHR and over half of the hospitals participating in all four interoperability domains (send, receive, find, and integrate) in 2019 (11).

Hematology

Automated Enumeration of Cell Populations

The last 40 years or so have been transformational for the clinical hematology laboratory, taking the enumeration of cell populations in the blood from a manual microscopic procedure to a highly sophisticated, automated process. The evolution of this process was initiated by the Coulter principle, which was defined by Wallace Coulter in early 1948 and which revolutionized the way we perform complete blood counts (CBCs) (12). The Coulter principle demonstrates that when cells suspended in an electrolyte solution are passed through a small aperture, they cause impedance to current flow or voltage pulses. The number of voltage pulses is related to the number of cells, and the amplitude of the signal is related to the cell volume. This principle paved the way for automated cell counting by the impedance method. In the decades that have followed, technology has progressed from cell counting and enumeration of red cell indices to a three-part white blood cell (WBC) differential count and later a five-part WBC differential.

Today, the modern hematology analyzer incorporates impedance, conductivity, optical absorbance, cytochemical detection, and basic flow-cytometric principles (forward and side scatter) to differentiate cell types. The addition of fluorescence detection has further enhanced the technology. Hydrodynamic focusing is another advancement of flow cytometry instrumentation adopted by modern hematology analyzers. In hydrodynamic focusing, the sample is injected into the analyzer surrounded by a sheath fluid that is flowing at a different velocity. This forces the cells to pass through the analyzer in single file and prevents multiple cells from passing through the aperture together and being counted as one. Without this technology, there is the potential for introducing a "coincidence error," which would result in an underestimation of the cell count.

White blood cell enumeration. The major manufacturers of today's hematology instrumentation utilize different combinations of these methods for enumerating cell populations in the CBC. There are, however, some subtle differences that differentiate the capabilities of different cell counters (13, 14). One of these analyzers relies on volume (impedance), conductivity, and laser light scatter measurements. The familiar impedance measurement estimates cell volume. Conductivity measurements involve determining the internal structure of the cell with a high-frequency current so that WBCs can be classified based on their cytoplasmic and nuclear content. Laser light scatter at 10- to 70-degree angles permits the differentiation of the granulocyte populations, with the extent of light scatter being related to granularity. This differentiates coarsely granular cells (basophils and eosinophils), which scatter more light, from finely granular cells (neutrophils). Other manufacturers use a combination of direct current and radio frequency measurements to perform a WBC differential count. Direct current (impedance) measurements provide an estimate of cell size, and radio frequency measurements determine nuclear size and density. This approach initially produces a three-part differential count (lymphocytes, monocytes, and granulocytes). Eosinophils and basophils are subsequently resolved from the neutrophils by differential temperature treatment using two different buffers. A further refinement of this technology uses a combination of radio frequency and direct current to detect chemical and electrical differences between immature and mature WBCs.

Multiangle polarized scatter separation is another approach to automated WBC differential analysis. An analyzer based on this principle uses a combination of small-angle forward light scatter and 90-degree (orthogonal) light scatter to differentiate the granulocyte populations. Neutrophils are differentiated from eosinophils, since the latter depolarize the 90-degree light scatter, while 10-degree light scatter discriminates basophils. An instrument principle different from the ones discussed so far is the basis of an analyzer that utilizes cytochemical staining in combination with forward-angle light scatter measurements. In contrast to the impedance method, the red blood cells (RBCs) and platelets are isovolumetrically sphered and fixed. The size or volume of the RBC is determined at low-angle light scatter (2 to 3 degrees), while the hemoglobin concentration within each RBC is determined by the absorbance at high-angle light scatter (5 to 15 degrees). Various red cell indices are subsequently calculated. Platelets and their volume (mean platelet volume) are computed from a plot of low-angle versus high-angle light scatter. After lysis of the RBC, a separate hemoglobin measurement is made by spectrophotometry as the released heme is reacted with cyanide to produce cyanomethemoglobin. Thus, the instrument provides both a total hemoglobin value and an estimate of the amount of hemoglobin within each RBC. Other manufacturers have moved away from using the cyanomethemoglobin method to direct photometry to avoid the issue of toxic waste associated with the cyanide reagent.

Other advances include automated nucleated RBC (nRBC) counts that do not interfere with the WBC count

本书版权归John Wiley & Sons Inc.所有

and automated reticulocyte analysis using fluorescent staining of RNA. The ability of a fluorescent dye to bind DNA within the nucleated RBC has been used to enumerate nRBCs (15). Differentiation of viable from nonviable cells is performed by the exclusion of a fluorescent dye such as propidium iodide, thus demonstrating an intact membrane. Furthermore, most hematology analyzers stain residual RNA within the reticulocytes with fluorescent or cytochemical dyes to provide a reticulocyte count as well as differentiating the immature reticulocyte fraction. This parameter can be used to distinguish iron deficiency from other causes of anemia, such as vitamin deficiency, thalassemia, bone marrow failure, or sickle cell disease (16).

Platelet measurements. Simultaneous measurement of the volume and the refractive index of platelets using two angles of laser light scatter has significantly improved platelet counting. By this two-dimensional analysis, platelet counts of less than 50×10^9/liter can be accurately and precisely measured, allowing discrimination between platelets and interfering nonplatelet particles (17). One manufacturer uses fluorescent staining to confirm platelet counts if the optical platelet count is in question (18). Enumeration of immature platelets has also been introduced, referred to as the immature platelet fraction (IPF). This parameter is helpful in discriminating thrombocytopenias due to decreased production (bone marrow disease) versus increased peripheral destruction, as in idiopathic thrombotic thrombocytopenia (ITP).

Over the past 20 years, the hematology laboratory has evolved from a lab with individual instruments that were manually loaded with samples to an automated laboratory with systems that incorporate multiple instruments to perform the automated CBC and differential, reflex to a slide for review or manual differential, and analyze and categorize cells on the smear. Erythrocytes can be sorted by their size, shape, and hemoglobin content, which is important when assessing hematological disorders (19). Clinicians may request a manual differential if an abnormal CBC is reported, but ongoing refinements in instrumentation that better categorize cells will improve patient diagnosis and workflow in the laboratory. This should also reduce the need for manual differentials performed by skilled morphologists. This is an important consideration given the significant shortage of skilled laboratory technologists that the profession is facing. Improvements in middleware will facilitate data analytics for prediction of patient outcomes as well as detecting trends and opportunities for lean laboratory workflow.

Quality images and faster slide scanning. Probably the most important technological advancement on the horizon is improvement in imaging, with better-quality images and faster slide scanning. With greater computing power, the ability to scan whole slides, analyze images, and provide CBC results in an acceptable time frame may be possible. As artificial intelligence continues to be applied to image analysis, improvements in cell categorization, and ultimately the ability to determine a diagnosis, will evolve. Although currently a weakness, instruments are being evaluated for the detection of *Plasmodium* species in the erythrocytes of malaria-infected individuals (20). One day, we may arrive at a point where very few samples require any manual intervention. If flow cytometry analysis using fluorescent markers for diagnosis of hematologic malignancies or other abnormalities can be incorporated into the automated hematology line and data analytics can process information with the CBC and differential, we may even be able to generate a relatively automated report defining the cell populations and disease classification. Table 48.2 summarizes the principles and some of the features of automated hematology analyzers.

Point-of-care testing. Until recently, one gap in laboratory hematology testing has been a true point-of-care device for performing a CBC with differential. This could be particularly useful in an outpatient office or clinical setting where near-patient CBC results could impact care and clinical outcomes. There are some small analyzers available, but until recently, none of them was CLIA waived (21). Most are of moderate complexity and require some technical expertise to use, thus limiting where

Table 48.2 Principles and common features of automated hematology instruments

Volume (impedance), conductivity, and laser light scatter
Direct current (impedance), radio frequency (nuclear size, cell density). Allows detection of chemical and electrical differences between immature and normal WBCs. Permits estimation of WBC immaturity. Can be used to enumerate nRBCs by dye binding of DNA.
Multiangle polarized light scatter. Measures percent nonviable WBCs by ability of live cells to exclude a fluorescent dye. Can be used to enumerate nRBCs by fluorescent dye binding of DNA.
Isovolumetric sphering, low- and high-angle light scatter, and cytochemical staining. Two-dimensional platelet counting by simultaneous measurement of volume and refractive index of platelets at two angles of laser light scatter. Can be used to enumerate reticulated platelets.
Most automated hematology analyzers can count and classify reticulocytes according to maturity.
An automated slide-maker (peripheral blood smear) is also an optional feature.
Variable ability to diagnose some infections with *Plasmodium* spp., the cause of malaria, and *Babesia* (particularly in cases with low parasitemia). Instruments may or may not be able to quantify the degree of infection (percent of cells infected). Challenges exist, and development of this technology continues.

本书版权归John Wiley & Sons Inc.所有

testing can be performed and increasing the regulatory oversight. A few manufacturers have attempted this feat, but only one has succeeded to date.

Molecular Testing

Molecular diagnostics in hematology include RNA and DNA analysis to detect and quantify genetic abnormalities and to determine disease heterogeneity. Molecular diagnostics have become very important in treating hematologic diseases for which targeted therapies are available. Delineating signaling pathways involved in common oncologic diseases and the effects of chromosomal translocations has allowed the development of many new pharmaceutical agents that target specific cellular messengers involved in signaling pathways of leukemias, lymphomas, and myelomas. In this regard, the laboratory's use of targeted genetic sequencing has become a core component in standard of care laboratory testing. As such, various manufacturers' iterations of the 21-gene assay and the 70-gene assay are recommended to determine genetic mutations, guide treatment options, and help determine prognoses.

Looking ahead to the next big advances in hematology testing, there are manufacturers developing instrumentation that can perform both the CBC and the differential, including what we now consider a manual differential, all on one instrument. This could greatly reduce the footprint in the laboratory and the amount of maintenance required while improving ease of use. Additionally, the ability to have near-patient or point-of-care CBCs and differential on an easy-to-use, CLIA-waived device could greatly improve patient care in certain settings. There are even companies evaluating cell phone apps for this. Imagine the improvement to care in resource-poor settings if a CBC could be done using a cell phone. And, if we really want to look to the future of laboratory evolution, required sample volumes may be smaller, or we may have minimally invasive devices that can identify cells *in vivo* as they pass by the device.

Chemistry

The clinical chemistry laboratory continues to be characterized by the common bread-and-butter types of assays that have been performed in chemistry laboratories for the past 25 years. These include but are not limited to electrolytes, basic metabolic panels, and hepatic, renal, and lipid panels. Advances in instrumentation have facilitated the movement of a multitude of tests into the "core" chemistry laboratory, such as those for tumor markers, therapeutic drugs, endocrinology, reproduction, drugs of abuse, and others. These assays are primarily composed of spectrophotometric chemical assays, enzymatic assays, and immunoassays (Table 48.3).

Table 48.3 Analytical principles and examples of analytes in clinical chemistry instruments

Analytical methodology	Common analytes[a]
Ion-selective electrodes	Sodium, potassium, chloride
Spectrophotometry	
Chemical reactions	Albumin, creatinine, iron, protein, phosphate
Fluorescence/ chemiluminescence	Hormones, tumor markers
Enzymatic reactions	Ammonia, CO_2, cholesterol, glucose, lactate
Enzyme measurements using substrates	ALT, AST, LDH, amylase, alkaline phosphatase, creatine kinase
Immunoassays	Beta-HCG, TSH, PTH, vitamin D, drugs, troponin
Freezing point depression	Serum osmolality, urine osmolality
Electrophoresis	Serum proteins, urine proteins, lipids

[a] ALT, alanine aminotransferase; AST, aspartate transaminase; HCG, human chorionic gonadotropin; LDH, lactate dehydrogenase; PTH, parathyroid hormone; TSH, thyroid-stimulating hormone.

Advances

Advances in clinical chemistry continue to be characterized by the development of more rapid and sensitive assays, improvements in computerization, and increased automation. New commercial assays are always in the developmental pipeline and include those for biomarkers of neurodegenerative diseases, kidney injury, autoimmune disorders, and other pathologies. Several manufacturers now offer an assay for cystatin C, an endogenous marker of renal function thought to be superior to creatinine (22). Existing assays continue to evolve with each new generation that is developed. For example, the high-sensitivity troponin assays recently approved by the FDA now measure circulating cardiac troponin levels in healthy individuals, not just those with myocardial infarction (23). Some manufacturers now offer rapid or "turbo" assays for cardiac troponin that require shorter incubation periods to achieve shorter turnaround times.

Manufacturers continue to develop faster instruments and often advertise an instrument's cycle time during sales promotions. However, the cycle time is only one contributor to result turnaround time, which is limited by the mechanics of probe washing, specimen handling, aspiration, transfer, dispensing, and cuvette wash operations. It is the combination of instrument cycle, assay incubation, and analyte measurement times that determines the total time required for a result. The time to the first result in an analytical run is highly dependent on the incubation time required by the specific assay, often between 5 and 20 minutes. If multiple specimens are loaded onto an instrument at once, sequential results will be reported

本书版权归John Wiley & Sons Inc.所有

about every 15 to 30 seconds after the first result. Consequently, high-throughput instruments are engineered with higher numbers of reaction cells so that numerous specimen reactions can occur simultaneously. Rapid test results require the combination of fast instruments, fast assays, and LIS interfacing.

Laboratory Computerization

Laboratory computerization continues to evolve, and many instruments are now manufactured with onboard QC software. Some onboard software includes Westgard QC rules, and QC reports with Levey-Jennings charts may now be printed directly from the instrument instead of through the LIS. In addition, some QC vendors offer software programs that allow a laboratory to compare any questionable QC results with results from other laboratories using the same lot of QC materials. The questionable QC results may be compared immediately due to the advent of instrument interfacing discussed above. Advances in computerization also allow LIS interfacing of instruments previously used for research use only. This has paved the way for the inclusion of high-performance liquid chromatography (HPLC) and liquid chromatography-mass spectrometry (LC-MS) into the mainstream clinical laboratory (24). Instrument manufacturers have responded with automated LC-MS systems that can perform preanalytical processing such as centrifugation and solid-phase extraction as well as analysis and reporting (25). These systems may include dual HPLC pumps for multiplexing and increased sample throughput, and electrospray ionization for positive and negative ionization to increase the numbers of analytes analyzed (26).

Laboratory Automation

Laboratories continue to seek automation of repetitive laboratory functions. In the preanalytical phase, these tasks often include specimen accessioning, sorting, centrifugation, volume measurement, aliquoting, and transport. The use of specimen barcodes allows rapid specimen accessioning via handheld or automated barcode readers. While numerous one-dimension and two-dimension barcodes exist, the one-dimension code known as code 39 was standardized across manufacturers, because it can be read even if placed on a specimen with a 30-degree tilt. As mentioned above, bidirectional interfacing makes it easier for preanalytical robotics to communicate with the LIS and determine if a specimen requires centrifugation. Most recently, digital cameras have been added to preanalytical robotics in order to verify appropriate tube type (cap color) as well as to determine adequate specimen volume. Analytical instruments continue to evolve in speed and function. Many instruments automatically perform specimen dilutions and reanalyze if analyte concentrations are higher than the analytical measurement range. Some instruments monitor the progression of specific assays to detect prozone errors and will warn operators of a potential hook effect. Postanalytical automation of the analytical results can provide increased accuracy via decreased transcription errors, result autoverification, and decreased TAT, all as a result of instrument interfacing. Postanalytical robotics can now store specimens in a refrigerated environment, retrieve stored specimens for add-on tests, and discard specimens after specified storage periods.

The future is likely to include increased sensitivity of current assays, assays to measure new disease biomarkers, and faster instrumentation.

Microbiology

Advances

The microbiology laboratory continues to be transformed by advances in automation, incorporation of mass spectrometry, and molecular tests for microorganisms. Commercially available automation systems are now available for the clinical microbiology laboratory. Most are modular systems that are customizable to fit each laboratory's sample volume and physical space. These revolutionary systems may include an automated sample decapper, pipettor, plate streaker, broth inoculator, CO_2 incubator, slide smearer, and plate reader. The automation of repetitive procedures promotes standardization, which tends to increase quality and efficiency while reducing costs. An example is the elimination of many preanalytical errors, such as mislabeled plates, incorrect media, and misplaced plates, which would have resulted in additional work and cost (27). Automating simple repetitive tasks can also free up highly skilled technologists so that they can attend to more technical duties. One laboratory determined that its microbiology plates were manually moved an average of five times between storage, incubators, benchtop, and waste, resulting in thousands of transfers per year that were eliminated with automation (27). The throughput of systems that perform automated plate streaking, incubator storage, and plate image analysis tends to be around 200 to 300 plates per hour (27). Laboratories with automated systems tend to observe shorter turnaround times for several reasons: (i) plates are routed to incubators immediately instead of sitting on benches in partially filled racks; (ii) automated incubators tend to hold more constant temperatures and CO_2 concentrations; and (iii) automated incubators read plates multiple times per day (28). Decreased incubation times allow urine cultures to yield results in as little as 10 hours and blood cultures in as little as 6 hours (29, 30). These and other advances are summarized in Table 48.4.

本书版权归John Wiley & Sons Inc.所有

Table 48.4 Features of automated microbiology instruments

Total laboratory automation may include plate selection, labeling, inoculation, transport, incubation, digital image analysis, and reporting functions.
Identification and antibiotic susceptibility testing. Cards of plates with embedded substrates are used for microbial identification antimicrobials as used for susceptibility determination. Turbidimetry is used to monitor microbial growth (decreased light transmittance) and to determine antibiotic susceptibility (increased light transmittance).
Chromogenic substrates for aerobic identification. A photometer performs kinetic fluorescence measurements every 15 minutes. Ninety-six-well plates are used to monitor growth and susceptibility via fluorescence measurement of substrates and antibiotics.
Automated blood culture systems determine CO_2 production via colorimetric, fluorescence, infrared, or radiometric detection.
Fast and accurate identification of microorganisms using time-of-flight mass spectrometry via mass-spectral libraries of cellular proteins.
Molecular identification of bacteria, viruses, and parasites using multiplexed panels with selective reporting/billing based on specific test order.

Microorganism Identification

Fast and accurate identification of microorganisms using mass spectrometry has recently made its way into the clinical laboratory. Numerous commercial mass spectrometers are available for microbiology use, and two systems are FDA approved at the time of this writing. Both utilize matrix-assisted laser desorption ionization–time-of-flight (MALDI-TOF) mass spectrometry to measure cellular proteins in order to identify specific microorganisms. The technology allows characterization of different families/subfamilies by the types and amounts of proteins they express, which allows construction of computerized libraries (31). MALDI-TOF analyzers with onboard libraries are able to identify Gram-positive and Gram-negative bacteria, fungi, and mycobacteria down to the genus and species levels (32), and this can be performed in less than an hour. This is significantly faster than the 6 to 48 hours required by traditional methods.

Molecular Microbiology

No analytical technique has transformed the microbiology laboratory more than the use of the real-time PCR in its qualitative and quantitative variations. The application of qPCR has transformed much of microbiology testing to molecular testing, and some laboratories now distinguish their traditional culture bacteriology lab from their molecular microbiology lab. The use of qPCR includes tests for bacteria, viruses, yeasts, and parasites responsible for respiratory infections, systemic (blood) infections, meningitis, gastroenteritis, and sexually transmitted diseases. These methods provide increased sensitivity, specificity, and more timely results, thereby reducing turnaround times by 10 to 20 hours (33, 34). Many of these methods incorporate multiplexing technology, which involves simultaneous detection of multiple analytes. Examples include assays for the simultaneous detection of over 20 respiratory viruses in nasopharyngeal swabs (35), more than 20 enteric pathogens in stool samples (36), and 15 pathogens in cerebrospinal fluid samples (37). Advantages of the multiplexing technology include the comprehensive nature of the panels and less labor required for the same results. Disadvantages of the comprehensive panels include the inclusion of targets not required in all patient scenarios as well as increased laboratory reagent cost for a comprehensive panel compared to a panel with few targets. However, given the improved sensitivity, specificity, and turnaround times associated with qPCR, laboratories will likely see the availability of additional qPCR assays in the future.

Blood Transfusion and Coagulation

Coagulation and Thromboelastography

Several new technologies have been developed in the blood transfusion/coagulation arena. The traditional tests used to guide blood transfusion include platelet concentrations, prothrombin time (PT), and partial prothrombin time (PTT). Thromboelastography (TEG) is a new test modality that provides a more complete picture of coagulation status by measuring time required for clot formation, clot elasticity, and clot volume (38). The TEG method samples whole blood from a patient's indwelling catheter and reports measurements every minute to provide the clinician with real-time information. No other technology can compete with TEG for the real-time determination of blood products needed to manage patients during critical care procedures, and TEG has been applied to obstetrics, surgery, trauma resuscitation, organ transplant, and perioperative care (39). TEG instruments are most commonly placed in or near critical-care areas such as intensive care units, emergency departments, and surgical suites, where they can provide rapid results. The importance of TEG was highlighted during the coronavirus disease 2019 (COVID-19) pandemic, as blood supplies became exhausted due to low donor participation. TEG monitoring was invaluable when hospitals enacted drastic measures for patient blood management, such as cell salvage and postsurgical reinfusion of the patient's blood (40). These and other new assays are listed in Table 48.5.

Inventory Tracking and Use

Some laboratories have recently adopted computerized dashboards or RFID (radio frequency identification) tagging systems for more efficient tracking of blood product inventory and use. Both technologies resulted in increased accuracy of blood product inventories and decreased the time required for manual inventorying by approximately

本书版权归John Wiley & Sons Inc.所有

Table 48.5 New assays and methods in blood transfusion/coagulation testing

Assays to monitor effects of clopidogrel, aspirin, and other platelet receptor inhibitors
Flow cytometry measurement of phosphorylation status of vasodilator-stimulated phosphoprotein and effect of clopidogrel
Assays to determine CYP2C19 mutations that affect clopidogrel metabolism
Microarray and electrochemical detection of CYP2C9 mutations that affect warfarin metabolism
Automated fluorescence-based methods to measure clot formation via thromboelastography

3 hours per day (41, 42). The use of RFID tracking also resulted in increased quality and patient safety by reducing patient morbidity and mortality and product loss (43).

Point-of-Care Testing

Computerization

Testing at the point of care is another modality that has been revolutionized by computerization. We now have point-of-care testing (POCT). While some desktop POCT systems still remain wired to the LIS via Ethernet cable, newer handheld systems for blood gases, basic chemistries, cardiac markers, coagulation, and hematologies now transmit results to the LIS via radio frequency (44). These test results populate the LIS almost immediately upon result determination. The battery life of handheld devices is limited but may be increased by toggling the unit to perform periodic polling every 2 to 5 minutes instead of constant communication. Security and result confidentiality continue to be chief considerations with any wireless system. Frequency hopping, secure Wi-Fi codes, and data encryption all apply (45) and should be discussed with the institution's IT team.

Rapid Assays

Advances in POCT systems continue to be characterized by new applications as well as improved and more rapid assays. Many hospitals now incorporate POCT in the operating room for patients with cardiac or pulmonary failure who require left ventricular assist devices (LVAD) or extracorporeal membrane oxygenation (ECMO) (46). These patients require heparin titrations during the procedures to mediate a fine balance between clotting and bleeding. The ability to determine PT, PTT, and the international normalized ratio (INR) at the bedside in the surgical suite greatly improves the management of these patients (47). As mentioned above, the use of TEG has moved into the surgical suite (39), which allows measurement and reporting of the blood's viscoelastic properties at the bedside.

POCT assays have recently been developed for numerous clinical applications. Tests include the detection of human papillomavirus (48), urinary tract infection (49), ovulation for family planning (50), serum lipids (51), drug abuse (52), and many others. POCT is generally effective for providing rapid results, with some caveats depending upon the design of the individual system. Some designs require a meter or device for result determination, which may or may not interface with the LIS. Some devices print results on thermal paper, whereas others do not. The lack of a paper trail or electronic result can result in human transcription errors. Still other designs require subjective visual determination of the results, which can lead to variability depending upon the user. Given the wide variability in device design, laboratory staff should be involved in the selection of devices to ensure the maintenance of quality results.

Improvements in POCT troponin assays have resulted in some now being classified as highly sensitive (53), meaning that these tests can measure circulating levels of cardiac troponin in healthy individuals. A new test for traumatic brain injury measures levels of glial fibrillary acidic protein and ubiquitin carboxyl-terminal hydrolase at the point of care to determine the need for brain computerized tomography scans (54). The recent development of POCT assays for hepatitis, tuberculosis, and sexually transmitted diseases could potentially transform treatment in outpatient clinics or public health settings (55). These and other improvements in POCT are listed in Table 48.6.

Developments during COVID-19

The medical and laboratory industry witnessed a rapid development of assays for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during the COVID-19 pandemic. Within a year of pandemic onset, lateral-flow antigen immunoassays, molecular amplification assays (56), and assays to detect human antibodies (57) had been developed and marketed to the public. These advances have facilitated developments in other areas of laboratory medicine. For example, a point-of-care device is now in production for the detection of *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis* in a disposable handheld qPCR device marketed for home use (58). Given these advances, rapid development of additional assays should be expected.

Table 48.6 Recent developments in point-of-care instruments, technologies, and assays

Hardwired and wireless interfacing with laboratory information systems
RT-PCR applications at the point of care
Optical and magnetic sensing of clot formation
New assays for hepatitis, tuberculosis, HIV, PT, PTT, INR, and cardiac troponin

本书版权归John Wiley & Sons Inc.所有

Molecular Diagnostics

Many dreams in the clinical diagnostics industry have recently become realities in the clinical laboratory. These include but are not limited to next-generation sequencing (NGS), whole-genome sequencing (WGS), loop-mediated isothermal amplification (LAMP), and biosensors for detection of bacteria and viruses. WGS allows the identification of viruses and their variant subclasses, which is necessary for monitoring viral mutations. If a virus does not reproduce an exact copy of its genomic sequence during the replication cycle, a genetic mutation occurs. A virus that mutates easily or one that mutates multiple times may spread to other species, may become more lethal, or both. The application of WGS became particularly important during the COVID-19 pandemic, during which laboratories were able to determine which SARS-CoV-2 variant affected the population at a given time (59). Information on the proportion of the population affected by one SARS-CoV-2 variant or another helped health experts predict transmissibility or lethality in the affected regions and facilitated their ability to guide public health policy (60). In addition to providing insight into the SARS-CoV-2 genetic code, WGS also provided details of its protein structure and stability, which were necessary for the development of effective mRNA vaccines against SARS-CoV-2 (61).

Real-Time PCR

Clinical laboratories have relied on real-time qPCR technology for the detection of viruses for several years, but its importance was pushed to the forefront in the laboratory's fight against SARS-CoV-2 during the COVID-19 pandemic. With its sensitive and specific detection of SARS-CoV-2 RNA, detailed qPCR methods were pushed out from the Centers for Disease Control and Prevention to state health department laboratories within days of the first COVID-19 cases presenting in the United States. Within several weeks, commercial qPCR assays for SARS-CoV-2 also became available in the United States. Many research and clinical laboratories that had qPCR capabilities implemented the CDC's method or developed their own methods *de novo* after acquiring the appropriate primers, signaling reagent, and master mix, a buffered solution containing the appropriate nucleic acids, enzymes, and cofactors. Many commercial qPCR assays required 4 to 8 hours for results, but the numbers of individuals affected by COVID-19 often resulted in emergency department overcrowding and a demand for high-throughput technologies. Manufacturers responded with accurate assays that could perform the necessary qPCR cycling, amplification, and detection in as little as 1 hour (62). Even more significant was the commercialization of LAMP analyzers that provided sensitive SARS-CoV-2 detection in less than 15 minutes (56). LAMP technology utilizes multiple primers to amplify the final signal 6-fold over that of traditional qPCR, resulting in very fast turnaround. Since the technology does not require a thermocycler, it could be housed in small inexpensive desktop units that may even be used at the point of care (63). These advances are summarized in Table 48.7.

Table 48.7 Applications and advances in molecular diagnostics

Whole-genome sequencing helps predict pandemic response.
Loop-mediated isothermal amplification facilitates inexpensive stand-alone virus detection.
Rapid RT-PCR facilitates virus detection in less than 1 hour.
Multiplexed test panels offer selective reporting/billing.

Outlook for the Future

Driving Forces

The hurdle of increasing costs faced by the current healthcare environment will drive the industry to stay on the cutting edge of innovation. It has been shown that the United States spends more than any other country on healthcare, but with little effect on patient outcomes (64). We live in an era of increasing costs of inpatient stays, laboratory tests, and clinician billing but shrinking reimbursements. These challenges could force the healthcare industry to do more with less, for example, reducing laboratory testing or improving clinicians' diagnostic abilities. However, innovators within the scientific community seek to increase efficiencies by eliminating unnecessary testing and adopting tests with increased sensitivity/precision so that diagnosis occurs earlier in the course of disease. In many diseases, earlier detection leads to improved patient outcomes and decreased financial burden on the healthcare system.

The quest for improved sensitivity and specificity has ushered in an era of personalized precision medicine, in which a patient's genetic makeup is determined so that his/her treatment can be optimized. For a number of years, genetic analysis of certain breast tumors prior to the commencement of chemotherapy has improved therapeutic responses (65). The genes that determine the rates of drug absorption, distribution, and metabolism are responsible for 30 to 95% of the variation in individuals' responses to drugs (66). As a result, the determination of genetic variants that predispose individuals to certain reactions to anticoagulants, opiates, antihypertensives, and other medications has proven beneficial and has improved patient outcomes. Further development in genetic and pharmacogenomic testing should be expected.

Expanding healthcare services to rural and underdeveloped areas is also an important step in reducing the burden of healthcare costs. Telehealth physician services can

本书版权归John Wiley & Sons Inc.所有

make a significant difference because they provide those in rural areas access to healthcare providers with reduced costs to the consumer. These services reduce the burden of travel for in-clinic visits, which in turn makes the clinic less crowded and more efficient (67).

Another mechanism to reduce the societal healthcare burden involves increased development of POCT. Innovations that increase the user-friendliness of lab tests will increase the ability to self-test. In this way, individuals can test at home and seek medical consultation if needed. Noteworthy examples include at-home POCT for measurement of glucose and cholesterol, assessment of thyroid function (68), and detection of celiac disease (69) and colon cancer (70), as well as the above-mentioned qPCR device for sexually transmitted diseases (55). We should expect additional POCT utilizing qPCR, as it is very sensitive and specific. The recent miniaturization of qPCR will have a significant effect on POCT.

Device Miniaturization

Advances in the computer industry and associated miniaturization will continue to affect the healthcare industry. Similar to the miniaturization of silicon computer chips, the increased application of microfluidics will facilitate the transference of laboratory-based tests to handheld and/or smaller devices. While the "lab on a chip" concepts initially triggered great excitement, significant challenges remain to be overcome (71). Miniaturized proof-of-concept immunoassay tests have demonstrated that sensing proteins in a nanofluidic environment significantly reduces result time due to the combination of shorter diffusion distances and efficient mass transfer. Miniaturization will likely first be adapted to POCT devices. A number of different sensors, such as those for sensing temperature, pressure, pH, oxygen, and chemicals, have also been incorporated into microfluidic chips (72), and these technologies have transitioned to the development of wearable sensors.

Similar to smart watches that measure heart rate and blood pressure, sensors have been developed for measuring circulatory glucose, reproductive hormones (73), and other analytes that may be monitored and recorded by smartphone apps. The apps may be programmed to alert the user or a loved one to a life-threatening condition, such as low glucose. In the future, we will likely see the commercialization of biosensors for viral detection. Small biosensors have been developed for the detection of SARS-CoV-2 and other viruses, with sensitivities on a par with that of qPCR at 100 copies of RNA per milliliter (74). Biosensors may be used to analyze various biological fluids, but saliva tends to be favored, as adequate volumes are easily obtained relatively noninvasively. Biosensors often utilize antibody capture or other capture mechanisms bound to graphene sheets of single-carbon thickness. The graphene sheets may incorporate antibodies to individual or multiple target analytes. Current nanoprinting technology allows the biosensor materials to be imprinted onto diverse types of hard or flexible materials. Recently, label-free techniques such as surface-enhanced Raman spectroscopy (SERS) have been used as biosensor detection mechanisms. SERS detects and quantifies light from unique molecular vibrations exhibited by analyte binding. This label-free detection technique eliminates the need for the secondary signaling reagents traditionally used in chemical, enzymatic, or electrochemical reactions and allows the development of wearable biosensors (75). Future biosensors may include those used to detect viruses in biological fluids as well as wearable devices or those that may be attached to walls or other surfaces for public screening. These and other developing diagnostics are listed in Table 48.8.

Table 48.8 Future technologies for clinical laboratory diagnostics

Additional applications for drug sensitivity testing of cancerous tumors
Increased genetic testing to predict predisposition to Alzheimer's disease, Crohn's disease, cardiovascular diseases, and various cancers
Additional pharmacogenetic analyses to predict abnormal responses to various pharmaceuticals and therapies
Increased applications of POCT devices for at-home use
Nanofluidic devices to identify bacteria and viruses and determine drug resistance
Increased use of telehealth systems and the potential for synchronous and/or automated reporting from wearable devices

SUMMARY

There is a strong trend toward increased automation in the clinical laboratory in order to increase efficiencies as well as to offset staffing shortages. Applications include those in the preanalytical, analytical, and postanalytical phases of laboratory testing. Molecular multiplexing technology is used to detect multiple bacterial, viral, or parasitic targets in a single analysis. Assays that include multiple analyte targets allow more comprehensive testing in a shorter time. Recently developed POCT devices for the detection of viruses or antibody responses exhibit adequate clinical sensitivity with more rapid results than traditional molecular techniques, and may be performed in clinical areas by non-laboratory staff. Future developments will include increased development of POCT tests, assay miniaturization, and wearable devices.

KEY POINTS

- The trend in the clinical laboratory is toward increased automation to include applications in the preanalytical, analytical, and postanalytical phases of laboratory testing.

本书版权归John Wiley & Sons Inc.所有

- Molecular multiplexing technology detects multiple bacterial, viral, or parasitic targets in a single assay. Some assays include over 20 analyte targets, which allows more comprehensive testing in a shorter time.
- Recently developed POCT devices for detection of viruses or antibody responses exhibit adequate clinical sensitivity with more rapid results than traditional molecular techniques.
- Future developments will include increased development of POCT tests, assay miniaturization, and wearable devices.

GLOSSARY

Autoverification Process involving computerized result verification that eliminates the manual review of results.

Centers for Medicare and Medicaid Services (CMS) U.S. federal agency that administers the Medicare program, Medicaid program, Children's Health Insurance Program, Health Insurance Portability and Accountability Act of 1996, Clinical Laboratory Improvement Amendments, and other federal programs.

Certified Electronic Health Record Technology (CEHRT) Set of electronic database criteria established to facilitate communication of patient healthcare information between clinicians, departments, and institutions for reimbursement by the federal Medicare program.

Coulter principle Method of counting and sizing blood cells via measurement of electrical conductivity across a small-diameter tube that cells pass through.

Delta check Quality control tool used to detect mislabeled specimens by comparing a patient's current laboratory results to the patient's previous results.

Electronic health record (EHR) Patient health information stored in a digital database format that may be shared with multiple hospital departments or institutions.

Extracorporeal membrane oxygenation (ECMO) Method of cardiac and respiratory support in which a patient's blood is pumped to an external artificial respirator to oxygenate the red blood cells.

Full-time equivalent (FTE) Management or accounting term that refers to a full-time position or full-time employee working 2,080 hours per year with full benefits.

Group purchasing organization (GPO) Group of institutions that have joined to negotiate lower purchase costs for commonly used items.

Health Level Seven (HL7) Computer protocol that specifies the order in which healthcare information (e.g., name, sex, age, and lab result) is transmitted in order to facilitate the transfer of information from one institution to another.

Heating, ventilation, and air conditioning (HVAC) A climate control system used to maintain appropriate environmental conditions for the workforce, instrumentation, and computers.

Immature reticulocyte fraction Percentage of immature reticulocytes in a patient's blood, determined for the purpose of detecting or monitoring disease.

Interface Programmable device that facilitates communication of the laboratory information system with a specific laboratory instrument or another software system.

International normalized ratio (INR) Patient's prothrombin time normalized to an international value. The INR is reported in order to standardize the prothrombin time due to differences in instruments and manufacturer's reagents. The normal INR value for normal individuals is 0.8 to 1.2, whereas the target range for individuals on anticoagulant therapy is 2.0 to 3.0.

Laboratory information system (LIS) Software system primarily used to store patient results. Laboratory information systems may also communicate with laboratory instruments as well as other software systems and may be used to monitor laboratory throughput and quality control and to derive calculated laboratory results.

Lateral-flow immunoassay Simple analytical test often used at the point of care. The test requires several drops of urine or blood placed on a wicking material housed in a plastic cartridge. The biologic material flows across the wick and interacts with antibodies in the device, which results in a color change reaction that is visually detected.

Lean processing Method of optimizing manufacturing efficiency by reducing nonvalue processes. Lean processing often reduces the number of times a specimen is touched, moved, or manipulated, as these functions may not add value.

Left ventricular assist device (LVAD) Computer-controlled mechanical pump used to increase cardiac output.

Logical Observation and Identifier Names and Codes (LOINC) Common language used to identify healthcare measurements, diagnoses, and laboratory results.

Loop-mediated isothermal amplification (LAMP) Analytical technique used to amplify and detect specific DNA or RNA targets while using a constant temperature.

Matrix-assisted laser desorption ionization (MALDI) Method of analyte ionization prior to mass spectrometry analysis in which a laser heats an acidic analyte mixture to cause the volatilization of ionized particles.

Molecular test panel Panel or group of analytes that may be individually detected during a single test utilizing a molecular technique. This may involve nucleic acid amplification, DNA sequencing, *in situ* hybridization, or other molecular analysis.

Next-generation sequencing (NGS) High-throughput sequencing technology in which multiple small DNA or RNA fragments are sequenced simultaneously. Use of NGS results in increased sequencing speed and decreased cost.

Perioperative care Patient care provided just prior to surgery, during surgery, and immediately after surgery.

Partial thromboplastin time (PTT) Laboratory test used to evaluate the intrinsic clotting cascade activated by factors in the blood.

Prothrombin time (PT) Laboratory test used to evaluate the extrinsic clotting cascade activated by tissue factor.

本书版权归John Wiley & Sons Inc.所有

Radio frequency identification (RFID) Form of wireless communication used to identify an object or an individual.

Real-time PCR (qPCR) Analytical technique that amplifies nucleic acids, measures the reaction products in real time, and provides qualitative or quantitative results. Quantitative tests may be used to determine the number of viral particles in a patient's blood (e.g., viral load) to monitor infection and/or treatment.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Single-stranded RNA virus that is transmissible to humans and responsible for the COVID-19 pandemic.

Thromboelastography (TEG) An analytical technique often used during surgical procedures to more accurately direct the use and administration of blood products. Thromboelastography measures multiple properties of clot formation, such as platelet aggregation, rapidity of clot formation, amplitude of clot formation, clot strength, and fibrinolysis.

Time-of-flight (TOF) mass spectrometry Analytical technique used to determine the mass/charge ratio of a molecule by measuring its time of flight through a vacuum tube of known length.

Total laboratory automation Process of automating all possible functions of the laboratory in the preanalytical, analytical, and postanalytical (data reporting) phases of laboratory testing.

Turnaround time (TAT) Time required to complete a procedure from start to finish. Laboratory turnaround time is often calculated from the time a specimen is received by the laboratory to the time of final result report. Total turnaround time may be calculated beginning with the time of test order.

U.S. Food and Drug Administration (FDA) Governmental agency established to protect and promote public health via oversight of foods, drugs, cosmetics, and medical devices.

White blood cell (WBC) count Quantitative analysis of the white blood cells in a patient's blood. The WBC count is commonly described as a 3-part, 5-part, or 7-part analysis. The type of instrumentation typically determines whether only neutrophils, lymphocytes, and monocytes are reported (3-part WBC) or whether basophils and eosinophils (5-part WBC) and immature granulocytes and atypical lymphocytes (7-part WBC) are included in the differential count.

Whole-genome sequencing (WGS) Analytical technique used to sequence an individual's genome that exhibits significantly increased accuracy over standard genetic tests. WGS is used to diagnose genetic disorders and has been shown to reduce healthcare costs by informing decisions regarding care and surgical procedures.

REFERENCES

1. **Durham J, Hackman S**. 2020. Better approaches to clinical laboratory design. *Clin Lab Manag* (July):32–35.

2. **Lippi G, Da Rin G**. 2019. Advantages and limitations of total laboratory automation: a personal overview. *Clin Chem Lab Med* **57**:802–811.

3. **Felder R**. 2006. Masahide Sasaki (obituary). *Clin Chem* **52**:791–792.

4. **Aller RD, Felder R**. 2007. Laboratory automation systems and workcells (survey). *CAP Today* **21**:30–48.

5. **Vercruysse K, Lambrecht S, Oyaert M**. 2021. Total lab automation: sample stability of clinical chemistry parameters in an automated storage and retrieval module. *Clin Chem Lab Med* **60**:52–59.

6. **Petrides AK, Bixho I, Goonan EM, Bates DW, Shaykevich S, Lipsitz SR, Landman AB, Tanasijevic MJ, Melanson SE**. 2017. The benefits and challenges of an interfaced electronic health record and laboratory information system: effects on laboratory processes. *Arch Pathol Lab Med* **141**:410–417.

7. **Lippi G, Plebani M**. 2016. Toxic alcohol concentrations and misinterpretation of laboratory results. *JAMA Intern Med* **176**:1228–1229.

8. **Topcu DI, Gulbahar O**. 2021. A model to establish autoverification in the clinical laboratory. *Clin Biochem* **93**:90–98.

9. **CMS**. 2012. Medicare and Medicaid programs; electronic health record incentive program-stage 2. Final rule. Centers for Medicare & Medicaid Services (CMS). *Fed Regist* **77**:53967–54162.

10. **U.S. Food and Drug Administration**. 15 June 2018. Logical Observation Identifiers Names and Codes for in vitro diagnostic tests. Guidance for industry and Food and Drug Administration Staff. https://www.fda.gov/media/113967/download. Accessed 19 March 2022.

11. **Johnson C, Pylypchuk Y.** 2021. Use of certified health IT and methods to enable interoperability by U.S. non-federal acute hospitals, 2019. ONC data brief, no. 54. https://www.healthit.gov/sites/default/files/page/2021-03/Hospital Use of Certified HIT_Interop v10_1.pdf. Accessed 19 March 2022.

12. **Davis BH, Barnes PW**. 2012. Automated cell analysis: principles, p 26–32. *In* Kottke-Marchant K, Davis BH (ed), *Laboratory Hematology Practice*. Blackwell Publishing, Ltd., Oxford, UK.

13. **Dabkowski B.** 2011. New applications, middleware, and more for hematology analyzers. *CAP Today* **25**:24–39.

14. **Ward PCJ**. 2000. The CBC at the turn of the millennium: an overview. *Clin Chem* **46**:1215–1220.

15. **D'Onofrio G, Zini G, Tommasi M, Van Hove L**. 1996. Integration of fluorescence and hemocytometry in the CELL-DYN 4000: reticulocyte, nucleated red blood cell, and white blood cell viability study. *Lab Hematol* **2**:131–138.

16. **Bó SD, Fragoso ALR, Farias MG, Hubner DPG, de Castro SM**. 2023. Evaluation of RET-He values as an early indicator of iron deficiency anemia in pregnant women. *Hematol Transfus Cell Ther* **45**:52–57.

17. **Chapman DH, Hardin J, Miers M, Moyle S, Kinney MC**. 2001. Reduction of the platelet review rate using the two-dimensional platelet method. *Am J Clin Pathol* **115**:894–898.

18. **Schoorl M, Schoorl M, Oomes J, van Pelt J**. 2013. New fluorescent method (PLT-F) on Sysmex XN2000 hematology analyzer achieved higher accuracy in low platelet counting. *Am J Clin Pathol* **140**:495–499.

19. **Ceelie H, Dinkelaar RB, van Gelder W**. 2007. Examination of peripheral blood films using automated microscopy; evaluation of Diffmaster Octavia and Cellavision DM96. *J Clin Pathol* **60**:72–79.

20. **Khartabil TA, de Rijke YB, Koelewijn R, van Hellemond JJ, Russcher H**. 2022. Fast detection and quantification of Plasmodium species infected erythrocytes in a non-endemic region by using the Sysmex XN-31 analyzer. *Malar J* **21**:119.

本书版权归John Wiley & Sons Inc.所有

21. Wu AHB, Sellers J. 2019. XW-100: first FDA CLIA-waived CBC analyzer designed for physician office use. *J Appl Lab Med* **3**:839–846.

22. Ostermann M, Zarbock A, Goldstein S, Kashani K, Macedo E, Murugan R, Bell M, Forni L, Guzzi L, Joannidis M, Kane-Gill SL, Legrand M, Mehta R, Murray PT, Pickkers P, Plebani M, Prowle J, Ricci Z, Rimmelé T, Rosner M, Shaw AD, Kellum JA, Ronco C. 2020. Recommendations on acute kidney injury biomarkers from the acute disease quality initiative consensus conference: a consensus statement. *JAMA Netw Open* **3**:e2019209.

23. Willeit P, Welsh P, Evans JDW, Tschiderer L, Boachie C, Jukema JW, Ford I, Trompet S, Stott DJ, Kearney PM, Mooijaart SP, Kiechl S, Di Angelantonio E, Sattar N. 2017. High-sensitivity cardiac troponin concentration and risk of first-ever cardiovascular outcomes in 154,052 participants. *J Am Coll Cardiol* **70**:558–568.

24. Edwards HD, Sabio H, Shihabi ZK. 2009. Rapid quantitation of hemoglobin S in sickle cell patients using the Variant II Turbo analyzer. *Ann Clin Lab Sci* **39**:32–37.

25. Stone J. 2016. High-throughput serum 25-hydroxy vitamin D testing with automated sample preparation. *Methods Mol Biol* **1378**:301–320.

26. Benton SC, Tetteh GK, Needham SJ, Mücke J, Sheppard L, Alderson S, Ruppen C, Curti M, Redondo M, Milan AM. 2020. Evaluation of the 25-hydroxy vitamin D assay on a fully automated liquid chromatography mass spectrometry system, the Thermo Scientific Cascadion SM clinical analyzer with the Cascadion 25-hydroxy vitamin D assay in a routine clinical laboratory. *Clin Chem Lab Med* **58**:1010–1017.

27. Thomson RB Jr, **McElvania E**. 2019. Total laboratory automation. What is gained, what is lost and who can afford it? *Clin Lab Med* **39**:371–389.

28. Mutters NT, Hodiamont CJ, de **Jong MD, Overmeijer HP, van den Boogaard M, Visser CE**. 2014. Performance of Kiestra total laboratory automation combined with MS in clinical microbiology practice. *Ann Lab Med* **34**:111–117.

29. De Socio GV, Di Donato F, Paggi R, Gabrielli C, Belati A, Rizza G, Savoia M, Repetto A, Cenci E, Mencacci A. 2018. Laboratory automation reduces time to report of positive blood cultures and improves management of patients with bloodstream infection. *Eur J Clin Microbiol Infect Dis* **37**:2313–2322.

30. Burckhardt I, Last K, Zimmermann S. 2019. Shorter incubation times for detecting multi-drug resistant bacteria in patient samples: defining early imaging time points using growth kinetics and total laboratory automation. *Ann Lab Med* **39**:43–49.

31. Heaton P, Patel R. 2018. Mass spectrometry applications in infectious disease and pathogens identification, p 93–114. *In* Rifai N, Horvath AR, Wittwer CT (ed), *Principles and Applications of Clinical Mass Spectrometry*. Elsevier, Amsterdam, Netherlands.

32. Sogawa K, Watanabe M, Sato K, Segawa S, Ishii C, Miyabe A, Murata S, Saito T, Nomura F. 2011. Use of the MALDI BioTyper system with MALDI-TOF mass spectrometry for rapid identification of microorganisms. *Anal Bioanal Chem* **400**:1905–1911.

33. Ward C, Stocker K, Begum J, Wade P, Ebrahimsa U, Goldenberg SD. 2015. Performance evaluation of the Verigene® (Nanosphere) and FilmArray® (BioFire®) molecular assays for identification of causative organisms in bacterial bloodstream infections. *Eur J Clin Microbiol Infect Dis* **34**:487–496.

34. Chong BSW, Kennedy KJ. 2021. Comparison of a commercial real-time PCR panel to routine laboratory methods for the diagnosis of meningitis-encephalitis. *Pathology* **53**:635–638.

35. Leber AL, Everhart K, Daly JA, Hopper A, Harrington A, Schreckenberger P, McKinley K, Jones M, Holmberg K, Kensinger B. 2018. Multicenter evaluation of BioFire FilmArray Respiratory Panel 2 for detection of viruses and bacteria in nasopharyngeal swab samples. *J Clin Microbiol* **56**:e01945–17.

36. Buss SN, Leber A, Chapin K, Fey PD, Bankowski MJ, Jones MK, Rogatcheva M, Kanack KJ, Bourzac KM. 2015. Multicenter evaluation of the BioFire FilmArray gastrointestinal panel for etiologic diagnosis of infectious gastroenteritis. *J Clin Microbiol* **53**:915–925.

37. Leli C, Di Matteo L, Gotta F, Vay D, Calcagno L, Callegari T, Cassinari M, Cattana E, Ciriello MM, Copponi V, Sacchi MC, Zambon D, Guaschino R, Rocchetti A. 2019. Diagnostic accuracy of a commercial multiplex PCR for the diagnosis of meningitis and encephalitis in an Italian general hospital. *Infez Med* **27**:141–148.

38. Collins S, MacIntyre C, Hewer I. 2016. Thromboelastography: clinical application, interpretation, and transfusion management. *AANA J* **84**:129–134.

39. Faraoni D, DiNardo JA. 2021. Viscoelastic hemostatic assays: update on technology and clinical applications. *Am J Hematol* **96**:1331–1337.

40. Shander A, Goobie SM, Warner MA, Aapro M, Bisbe E, Perez-Calatayud AA, Callum J, Cushing MM, Dyer WB, Erhard J, Faraoni D, Farmer S, Fedorova T, Frank SM, Froessler B, Gombotz H, Gross I, Guinn NR, Haas T, Hamdorf J, Isbister JP, Javidroozi M, Ji H, Kim YW, Kor DJ, Kurz J, Lasocki S, Leahy MF, Lee CK, Lee JJ, Louw V, Meier J, Mezzacasa A, Munoz M, Ozawa S, Pavesi M, Shander N, Spahn DR, Spiess BD, Thomson J, Trentino K, Zenger C, Hofmann A, International Foundation of Patient Blood Management (IFPBM) and Society for the Advancement of Blood Management (SABM) Work Group. 2020. Essential role of patient blood management in a pandemic: a call for action. *Anesth Analg* **131**:74–85.

41. Woo JS, Suslow P, Thorsen R, Ma R, Bakhtary S, Moayeri M, Nambiar A. 2019. Development and implementation of real-time web-based dashboards in a multisite transfusion service. *J Pathol Inform* **10**:3.

42. Dusseljee-Peute LW, Van der Togt R, Jansen B, Jaspers MW. 2019. The value of radio frequency identification in quality management of the blood transfusion chain in an academic hospital setting. *JMIR Med Inform* **7**:e9510.

43. Briggs L, Davis R, Gutierrez A, Kopetsky M, Young K, Veeramani R. 2009. RFID in the blood supply chain—increasing productivity, quality and patient safety. *J Healthc Inf Manag* **23**:54–63.

44. Chen J, Gorman M, O'Reilly B, Chen Y. 2016. Analytical evaluation of the epoc® point-of-care blood analysis system in cardiopulmonary bypass patients. *Clin Biochem* **49**:708–712.

45. Johannis W, Bietenbeck A, Malchau G, Streichert T. 2020. Point-of-care testing (POCT) and IT security concepts. *J Lab Med.* **44**:107–111.

46. Bercovitz RS. 2018. An introduction to point-of-care testing in extracorporeal circulation and LVADs. *Hematology (Am Soc Hematol Educ Program)* **2018**:516–521.

本书版权归John Wiley & Sons Inc.所有

47. Wool GD. 2019. Benefits and pitfalls of point-of-care coagulation testing for anticoagulant management: an ACLPS critical review. *Am J Clin Pathol* **151**:1–17.

48. Van Keer S, Peeters E, Vanden Broeck D, De Sutter P, Donders G, Doyen J, Tjalma WAA, Weyers S, Vorsters A, Arbyn M. 2021. Clinical and analytical evaluation of the RealTime High Risk HPV assay in Colli-Pee collected first-void urine using the VALHUDES protocol. *Gynecol Oncol* **162**:575–583.

49. Arienzo A, Cellitti V, Ferrante V, Losito F, Stalio O, Murgia L, Marino R, Cristofano F, Orrù M, Visca P, Di Somma S, Silvestri L, Ziparo V, Antonini G. 2020. A new point-of-care test for the rapid detection of urinary tract infections. *Eur J Clin Microbiol Infect Dis* **39**:325–332.

50. Weddell S, Jones GL, Duffy S, Hogg C, Johnson S, Ledger W. 2019. Home ovulation test use and stress during subfertility evaluation: subarm of a randomized controlled trial. *Womens Health (Lond Engl)* **15**:1745506519838363.

51. Ning Y, Lu F, Liu Y, Yang S, Wang F, Ji X, He Z. 2021. Glow-type chemiluminescent hydrogels for point-of-care testing (POCT) of cholesterol. *Analyst (Lond)* **146**:4775–4780.

52. Scherer JN, Schuch JB, Rabelo-da-Ponte FD, Silvestrin R, Ornell R, Sousa T, Limberger RP, Pechansky F. 2020. Analytical reliability of four oral fluid point-of-collection testing devices for drug detection in drivers. *Forensic Sci Int* **315**:110434.

53. Wildi K, Boeddinghaus J, Nestelberger T, Lopez-Ayala P, Yufera Sanchez A, Okamura B, Shrestha S, Rohner J, Miró Ò, Martinez-Nadal G, Martin-Sanchez FJ, Koechlin L, Twerenbold R, Christ M, Kawecki D, Rubini Giménez M, Keller DI, Mueller C, for the APACE Investigators. 2022. 0/2 h-algorithm for rapid triage of suspected myocardial infarction using a novel high-sensitivity cardiac troponin I assay. *Clin Chem* **68**:303–312.

54. Biberthaler P, Musaelyan K, Krieg S, Meyer B, Stimmer H, Zapf J, von Matthey F, Chandran R, Marino JA, Beligere G, Hoffmann M, Zhang H, Datwyler SA, McQuiston B. 2021. Evaluation of acute glial fibrillary acidic protein and ubiquitin c-terminal hydrolase-L1 plasma levels in traumatic brain injury patients with and without intracranial lesions. *Neurotrauma Rep* **2**:617–625.

55. Bernardini S, Pieri M, Ciotti M. 2021. How could POCT be a useful tool for migrant and refugee health? *EJIFCC* **32**:200–208.

56. James AS, Alawneh JI. 2020. COVID-19 infection diagnosis: potential impact of isothermal amplification technology to reduce community transmission of SARS-CoV-2. *Diagnostics (Basel)* **10**:399.

57. Shalaby A, Laharwani H, Bates JT, Kyle PB. 2021. Efficacy of POC antibody assays after COVID-19 infection and potential utility for "immunity passports." *Lab Med* **53**:262–265.

58. Morris SR, Bristow CC, Wierzbicki MR, Sarno M, Asbel L, French A, Gaydos CA, Hazan L, Mena L, Madhivanan P, Philip S, Schwartz S, Brown C, Styers D, Waymer T, Klausner JD. 2021. Performance of a single-use, rapid, point-of-care PCR device for the detection of Neisseria gonorrhoeae, Chlamydia trachomatis, and Trichomonas vaginalis: a cross-sectional study. *Lancet Infect Dis* **21**:668–676.

59. Laha S, Chakraborty J, Das S, Manna SK, Biswas S, Chatterjee R. 2020. Characterizations of SARS-CoV-2 mutational profile, spike protein stability and viral transmission. *Infect Genet Evol* **85**:104445.

60. Oude Munnink BB, Nieuwenjuijse DF, Stein M, O'Toole A, Haverkate M, Mollers M, Kamga SK, Schapendonk C, Pronk M, Lexmond P, van der Linden A, Bestebroer T, Chestakova I, Overmars RJ, van Nieuwkoop S, Molenkamp R, van der Eijk AA, Geurtsvan Kessel C, Vennema H, Meijer A, Rambaut A, van Dissel J, Sikkema RS, Timen A, Koopmans M, Dutch-Covid-19 response team. 2020. Rapid SARS-CoV-2 whole-genome sequencing and analysis for informed public health decision-making in the Netherlands. *Nat Med* **26**:1405–1410.

61. Paul D, Pyne N, Paul S. 2021. Mutation profile of SARS-CoV-2 spike protein and identification of potential multiple epitopes within spike protein for vaccine development against SARS-CoV-2. *Virusdisease* **32**:703–726.

62. Loeffelholz MJ, Alland D, Butler-Wu SM, Pandey U, Perno CF, Nava A, Carroll KC, Mostafa H, Davies E, McEwan A, Rakeman JL, Fowler RC, Pawlotsky JM, Fourati S, Banik S, Banada PP, Swaminathan S, Chakravorty S, Kwiatkowski RW, Chu VC, Kop J, Gaur R, Sin MLY, Nguyen D, Singh S, Zhang N, Persing DH. 2020. Multicenter evaluation of the Cepheid Xpert Xpress SARS-CoV-2 test. *J Clin Microbiol* **58**:e00926-20.

63. Gerlier C, Pilmis B, Ganansia O, Le Monnier A, Nguyen Van JC. 2021. Clinical and operational impact of rapid point-of-care SARS-CoV-2 detection in an emergency department. *Am J Emerg Med* **50**:713–718.

64. Kumar S, Ghildayal NS, Shah RN. 2011. Examining quality and efficiency of the U.S. healthcare system. *Int J Health Care Qual Assur* **24**:366–388.

65. Singer CF. 2021. Genetic testing in breast cancer: new standards of care. *Breast Care (Basel)* **16**:193–195.

66. Prodan Žitnik I, Černe D, Mancini I, Simi L, Pazzagli M, Di Resta C, Podgornik H, Repič Lampret B, Trebušak Podkrajšek K, Sipeky C, van Schaik R, Brandslund I, Vermeersch P, Schwab M, Marc J, EFLM/ESPT working group of Personalised Laboratory Medicine. 2018. Personalized laboratory medicine: a patient-centered future approach. *Clin Chem Lab Med* **56**:1981–1991.

67. Serir N, Pilat S, Pouget R, Errouane B. 2022. [Telemedicine and emergency medicine]. *Rev Med Suisse* **18**:1507–1511.

68. Di Cerbo A, Quagliano N, Napolitano A, Pezzuto F, Iannitti T, Di Cerbo A. 2021. Comparison between an emerging point-of-care tool for TSH evaluation and a centralized laboratory-based method in a cohort of patients in southern Italy. *Diagnostics (Basel)* **11**:1590.

69. Oehme R, Sandholzer-Yilmaz AS, Heise M, Frese T, Fankhaenel T. 2022. Utilization of point-of-care tests among general practitioners, a cross-sectional study. *BMC Prim Care* **23**:41.

70. Hathway JM, Miller-Wilson LA, Sharma A, Jensen IS, Yao W, Raza S, Parks PD, Weinstein MC. 2021. The impact of increasing multitarget stool DNA use among colorectal cancer screeners in a self-insured US employer population. *J Mark Access Health Policy* **9**:1948670.

71. Cheriyedath S. 2021. What is lab-on-a-chip? AZO Life Sciences. https://www.azolifesciences.com/article/What-is-Lab-on-a--Chip.aspx. Accessed 15 August 2022.

72. Dietrich TR. 25 June 2020. Microfluidics technology's growing importance in healthcare and the search for fast-acting Covid-19 test kits. NS eMedical Devices. https://www.nsmedicaldevices.com/analysis/microfluidics-healthcare-covid-19-test-kits/. Accessed 15 August 2022.

本书版权归John Wiley & Sons Inc.所有

73. Nulty AK, Chen A, Thompson AL. 2022. The Ava bracelet for collection of fertility and pregnancy data in free-living conditions: an exploratory and validity acceptability study. *Digit Health* **8**:20552076221084461.

74. Agarwal DK, Nandwana V, Henrich SE, Josyula VPVN, Thaxton CS, Qi C, Simons LM, Hultquist JF, Ozer EA, Shekhawat GS, Dravid VP. 2022. Highly sensitive and ultra-rapid antigen-based detection of SARS-CoV-2 using nanomechanical sensor platform. *Biosens Bioelectron* **195**:113647.

75. Paria D, Kwok KS, Raj P, Zheng P, Gracias DH, Barman I. 2022. Label-free spectroscopic SARS-CoV-2 detection on versatile nanoimprinted substrates. *Nano Lett* **22**:3620–3627.

本书版权归John Wiley & Sons Inc.所有

49

Introduction

Trends Impacting the Field of Clinical Pathology

Difficulty in Finding Laboratory Staff Workforce • Computation • Increasing Patient Access • Going Remote

Response of the Pathology Department to Recent Trends

Informatics and Artificial Intelligence • Automation • Laboratory Consultation • Remote Ready

Laboratory Principles To Live By

Accuracy and Reliability • Scalability • Coordination • Flexibility

SUMMARY

KEY POINTS

GLOSSARY

REFERENCES

The Future Practice of Laboratory Medicine

Christopher Zahner and Peter McCaffrey

OBJECTIVES

To acquaint the reader with trends and forces shaping clinical pathology

To predict directions for evolution of clinical pathology

It amounts to a truism to say that progress in the practical arts of medicine in any of its branches, whether preventive or curative, only comes from the growth of accurate knowledge as it accumulates in the laboratories and studies of the various sciences.

Walter M. Fletcher (1)

Before the year 1900, clinicians relied almost exclusively on patient history and physical examination to make medical diagnoses. However, innovations in chemistry, physics, fluidics, and computation have revolutionized laboratory medicine, leading to a greater emphasis on these fields in clinical medicine. As of the year 2000, clinicians used information from the clinical laboratory for most of their diagnoses (2). The trend of increasing clinical dependence on the laboratory to make diagnostic decisions seems likely to continue for the foreseeable future.

Pathology departments are usually a combination of clinical and anatomic subspecialties in the United States. However, historically, this pairing has not always been evident, and on a worldwide scale, it is often absent. Much to the chagrin of clinical pathologists, because anatomic pathology has a clearly defined role in analysis, it has been more appropriately compensated, making anatomic pathology a far more compelling and lucrative selection for medical graduates, which potentially explains its numerical superiority.

Traditionally, the role of the clinical laboratory has been 2-fold: (i) to perform simple and complex laboratory tests on patient specimens and (ii) to assist in the selection of these tests (3, 4). Despite the obvious potential advantages of these functions in medicine, they pose a challenge for medical payors attempting to reimburse for them. Oversight of laboratory testing is challenging to quantify, just as "appropriate test selection" can be nebulous. The adage "What gets measured gets managed" may be applicable here, as the effectiveness of clinical pathology functions may be too challenging to measure accurately and therefore compensate adequately. As we see here, data analytics, the flexibility to address emerging medically related situations (such as pandemics), clinical optimization, and cost savings are likely to play a more prominent role in future medical practice, rendering the clinical laboratory's effectiveness much more valuable in the future.

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch49.

本书版权归John Wiley & Sons Inc.所有

This chapter discusses many of the external forces affecting clinical pathology and makes predictions about the best way for the field to respond by positioning itself to thrive in the decades to come.

Trends Impacting the Field of Clinical Pathology

Difficulty in Finding Laboratory Staff Workforce

Medical experts have been concerned about the training and number of laboratory professionals for decades. Unfortunately, current trends make their earlier predictions appear prescient, if not dire. The Bureau of Labor Statistics has projected a nationwide shortage over the next 10 years (5). The growth rate of the field is 11 to 13%, which is greater than the national average for new jobs. Overall, recruitment and training will account for only half of the total new hires needed, because the laboratory workforce, in general, is getting older and nearing retirement. An American Society for Clinical Pathology (ASCP) study recently found that the average age of medical technologists has stayed elevated or increased while the percentage of unemployed laboratory technologists has decreased (6). Nationally, labor costs are going up, and unfortunately, the labor costs in the lab are rising too fast for us to keep up.

The clinical need for laboratory services has increased primarily due to population growth in the United States. Patients beyond or near retirement age use medical services at a much higher rate than younger patients, and chronic conditions that occur in older patients are often diagnosed at a much higher rate.

The ASCP conducted a vacancy survey for the year 2020 and received responses from 476 respondents across the United States. The core laboratory vacancy rate is 10.3%, or nearly double the national average. The rest of the laboratory fared not much better, with vacancy rates of 12.7% for chemistry and 8.5% for hematology. The anticipated 5-year retirement rate for all departments was 17.9% (7). With the consistently troubling trend of difficulty in hiring appropriate candidates, pathology departments will need to address the shortfall of qualified candidates using many different techniques.

Computation

It is often said that 70% of clinical decisions are based upon laboratory testing. As the test menu broadens and becomes increasingly complex, this number seems likely to grow. The advent of liquid biopsy and pharmacogenomics, the use of more extensive multiplexed antibody testing, and the increased portability of chemistry testing to the point of care are just a few examples of the drivers that make clinical decision making increasingly intertwined with laboratory testing. Although the test menu continues to grow, laboratory testing benefits from the fact that test-related data, including standardized interpretive result comments, are easier to aggregate and mine than medical data from other sources, such as clinical notes. Within the complex landscape of the electronic medical record (EMR), the laboratory information management system (LIMS) and the computerized provider order entry system (CPOE) provide useful abstractions in the form of test orders, test components, numerical test results, and qualitative test interpretations and commentary that can be aggregated from medical data systems much more easily than the linguistics of progress notes. Thus, laboratory information is a rich source for data warehousing and modeling for a variety of diagnostic and prognostic uses. In fact, computation has existed for some time in this area, with algorithms having been used for many decades. As we look forward to the next few decades, the trends in enterprise-level data warehousing combined with the favorable properties of clinical laboratory data will place pathology informatics at the forefront of healthcare data science and machine learning, which is discussed in greater detail later in this chapter.

Advances in computation. There are also significant advances in computation happening with analyzer instrumentation itself. We have likely all observed the physical advancements in terms of microfluidics, internal automation, and standardization of kits, reagents, and tubes that allow instruments to perform more tests at lower cost, and we routinely benefit from these advancements, largely but not exclusively those related to automated chemistry and hematology analyzers. Likewise, there are important informatics and computational trends playing out with instrumentation as well. First, their codevelopment with LIMSs and native interoperability with messaging test results mean that this increased throughput in test execution results in increased volumes of numerical data that arrive in data warehouses, wherein they are available for downstream modeling uses. Second, we have seen a continued integration of machine learning into analyzer instrumentation, giving rise to features such as the ability to create automatic blood smears and to derive categorized cell images from that smear. Third, we have seen new instrumentation platforms leverage both computational and physical technologies aimed at making test performance more computationally driven. An illustrative example of this is the creation of smaller, at-home blood analyzers which favor imaging and computer vision not just for blood cell classification but also for identification of malaria and trypanosomiasis, and even for calculation of other red blood cell parameters traditionally tested through dedicated physical means like impedance. This sort of computationally driven platform consolidation is also evident in the maturation of genomics testing. Here, the

本书版权归John Wiley & Sons Inc.所有

success of DNA sequencing has driven its use from profiling genes to sequencing RNA to epigenetic testing, and even in more exotic use cases like DNA-encoded library screening or high-throughput proteomics, wherein DNA is used to barcode chemicals and proteins, DNA sequencing instrumentation is used to perform the primary measurement, and computational tools are used to sort this information out after the fact. An important consequence of this technical consolidation is that it expands the range of applications for machine learning in laboratory testing. For example, computer vision continues to see brisk development outside healthcare, and within pathology, its reach has focused primarily on histology. However, as more analyzers implement computer vision technology, these models and their related tools become applicable to other areas, such as hematology analysis. Likewise, genomics tools continue to develop at a rapid pace, and the expansion of genomics as a common test platform means that computational approaches which would previously have focused on describing patient DNA can now be applied to transcriptomics, epigenetics, proteomics, and clinical diagnostic laboratory disciplines.

Finally, we also see the capacity of computational approaches for anomaly detection and prediction to identify disease before symptoms might drive patients to a hospital. Thus, pathology-centric computation embedded in things such as apps integrated in cell phones and wearable devices will most likely grow in importance as perhaps the first touchpoint for identifying disease in patients and prompting them to seek clinical care. The uses for such "edge" computation range from detecting trends toward anemia as an early indicator of colon cancer to providing prompt feedback on the success of cholesterol or glucose management efforts. Indeed, tests such as the aforementioned liquid biopsy are also primary examples of advanced computation performed on outpatient peripheral blood that can provide rich diagnostic information. However, computational tools may remain within companies that offer this testing as a send-out option.

Increasing Patient Access

On 5 April 2021, the U.S. federal government implemented the 21st Century Cures Act, which specifies that several types of clinical information must not be blocked and must be made available to patients. In addition, patient medical information is to be provided "without delay" (8).

Access to medical information empowers patients to achieve better health outcomes. However, primarily to reduce work effort and simplify clinical practice, the medical establishment has historically restricted access to patient information. Although many patients perceive expanded information as beneficial, medical challenges resulting from this information dissemination have become apparent (9–14).

A significant challenge for proper medical care in this new era of easy and fast information flow to patients is that they often see testing results before their clinical doctor. No longer is time available for the clinical team to process and react to diagnostic results. Now, patients see test outcomes and may demand immediate responses to them. Patients may be confused when interpreting test results without the proper clinical context. Therefore, it is the responsibility of the laboratory and/or diagnostician to interpret every result put into the electronic medical record for the proper understanding of their patients. M.D. pathologists and Ph.D. technical directors cannot remain only in the laboratory; we must communicate directly with patients now.

Going Remote

Ever the dream of the introverted academic, living and working separated from colleagues and remaining free to immerse oneself in the highly complex is a dream for many. However, while the world grappled with the immense challenges of the global supply chain shutdown and the medical, logistical challenges that the coronavirus disease 2019 (COVID-19) pandemic posed, many white-collar workers were living their best lives at home, happily churning out productivity. The rapid replacement of office work with virtual work has been a minor miracle, and it has allowed the world's economy to pivot swiftly and recover much faster than anticipated.

Many people have begun to enjoy this new lifestyle, preferring either complete or partial remote work (15). While many workers are very excited about the "work-from-anywhere" concepts present in the knowledge work environment, new challenges persist, such as loneliness, separation, and collaboration challenges that were not nearly as daunting in years past. Record numbers of knowledge workers face depression and anxiety to levels not seen previously. Much of the blame can be associated with the loneliness of working from home and decreased collaboration effectiveness (16).

Pathology departments are uniquely positioned to take advantage of this remote working environment. Still, they will need to be wary of the challenges to maintain and improve the working conditions for faculty and staff.

Response of the Pathology Department to Recent Trends

Informatics and Artificial Intelligence

Given the increasing role of laboratory medicine in healthcare, the development of automation, the likely increases in test utilization, and the ease with which laboratory data can be collected and organized, the value of artificial intelligence (AI) to pathology is difficult to overstate. While a detailed investigation of the field of AI is beyond the scope

本书版权归John Wiley & Sons Inc.所有

of this book, it is helpful to review some basic concepts. Briefly, AI describes the broad pursuit of building tools that can receive data from their environment and can respond to those data according to some policy. In the case of machine learning, this policy is a function that maps inputs to outputs, and this function is "learned" by "training," which is an iterative process wherein a machine learning model's outputs are compared to ground truth, the errors between predictions and ground truth are measured, and the model's function is modified so as to reduce this error. As machine learning focuses on creating accurate models through training, its success is notoriously dependent both on having ample quantities of training data and on having those data represent the types of entities a successful model would be expected to see in practice (17). Meeting these requirements ensures that a trained model will successfully generalize, meaning that it will operate successfully on real inputs it has not exactly seen in training.

Machine learning. Machine learning models themselves can be simple, as in the case of linear regression, or complex, as in the case of neural network models. Moreover, models are typically selected according to the type of input data received and the specific modeling task being desired. Many potential healthcare uses for AI require at least moderately complex models, as they typically include analysis of images or language. Because laboratory testing generates comparatively well-formatted numerical data and contains a breadth of modeling tasks ranging from the simple (e.g., "is this test result an anomaly") to the complex (e.g., "based upon this patient's last 6 days of testing, what is the risk that acute kidney injury will develop in the next 48 hours?"), it represents one of the most attractive and promising domains for the application of AI across the full spectrum of complexity.

Furthermore, the motivations for AI's use in healthcare are becoming increasingly significant: there are more tests and more patients with relatively fewer physicians with relatively less time available to think about those results and to either personally formulate care plans or personally catch potential errors or oversights. Thus, the narrow application of AI to create tools that aid in diagnosis through alerts such as impending acute kidney injury (18) or iatrogenic anemia or that identify potential errors such as wrong-blood-in-tube events (WBITs) is increasingly needed in order to support physician practice amidst a falling ratio of doctors to patients. Second, AI has myriad uses—especially in the clinical laboratory—for identifying practice variability and even remediating such variability by recommending more common or orthodox practice behaviors. This is both a critical need and one that laboratory data's proximity to test order and result feeds make it uniquely suited to handle.

Going further, there are a number of more advanced AI application areas that are emerging from the clinical laboratory and adjacent anatomic pathology domains. Before discussing these, it is helpful to review two concepts that are extensions of the introduction to machine learning (above): deep learning and reinforcement learning. Deep learning is a subcategory of machine learning wherein the functions used to map inputs to outputs are of a specific category known as neural networks. Deep learning is notable for its capacity to learn complex models and to pick up on subtle and generally nonobvious attributes of input data that are useful for prediction and classification. For example, creating a rules-based model for identifying cancer in a histology image may seem initially straightforward but becomes elusive in practice, given the sheer number of exceptions, edge cases, and conditional circumstances that such a model would require. When the question "what is it about the pixels in this image that tells us there is cancer here?" is asked, pinning down simple and specific answers is challenging given that neoplastic cells can have different shapes, sizes, spatial distributions, etc. More abstract notions like "atypia" are intuitive but almost impossible to express explicitly (19). This is where the capabilities of deep learning have demonstrated significant value. From an image of pixels, such models are in fact able to learn functions that can usefully distinguish cancer from benign tissue (among other applications), even if such functions are extraordinarily complex. This, of course, comes at the cost of reduced interpretability, but the fact that this allows for the automated scale-up of formerly human-centric tasks like slide triage and detection of lymph node metastases means that such tools—even if automating a narrow task—will almost certainly grow to be a ubiquitous component of the anatomic pathologist's workflow.

Finally, reinforcement learning is another subtype of machine learning which may use neural networks (in the case of deep reinforcement learning) but does not have to and is itself defined by the selection of model inputs and outputs. As such, the setup of a reinforcement learning task is that one seeks to create an agent that continually samples snapshots of its environment and continually uses those snapshots to refine and update a policy of action. In fact, we have seen reinforcement learning applied to optimize both warfarin dosing and titration of heparin drips, as the "environment" can be constructed as a series of coagulation test results. We will likely see much more development in this area as reinforcement learning becomes increasingly mainstream.

Automation

The future of clinical laboratory automation will involve the receipt, delivery, and processing of laboratory specimens using a wide array of testing analyzers. In addition, laboratories will store samples for later retrieval for

本书版权归John Wiley & Sons Inc.所有

trending analysis. All of this will be accomplished without direct human oversight and will increase the rate of and need for laboratory testing to an unprecedented level.

Automation is the use of hardware and equipment in a system of manufacturing or another process for the purposes of reducing labor expenditure. Perhaps the earliest automation system in human history was the bow and arrow. This system leverages increased human cognition to physically remove the person from the hunting action. However, by "preloading" the bow, the hunter could release the arrow, and the movement of the hunt could proceed without the hunter's continued involvement. This step represents an incredible advance in cognitive evolution and left a path that humans have attempted to follow ever since.

The clinical laboratory has become one of the world's most reliable and responsive environments. Tens of millions of specimens routinely pass through our clinical laboratories at hundreds of locations around the country. Nearly every one of those specimens is accurately tracked and analyzed, and results posted. These accurate results lead to an unprecedented level of clinical care for our patients. However, unfortunately, the need for more testing from the clinical laboratory appears nearly endless.

Computer and mechanical automation systems have been increasingly relied upon to address the need for increased accuracy, reliability, and speed. At present, clinical laboratory automation systems are bulky. Laboratories have built many automation systems to deliver specimens into and out of the clinical chemistry division. Smaller automation systems add other divisions, such as hematology and microbiology. Due to smaller testing volumes, higher complexity per test, and more specialization required by the laboratory technologists, laboratories largely neglect smaller service lines in favor of manual workflows. However, limiting of automation is unlikely to persist, and automation is likely to permeate the laboratory, as has occurred in other industries.

Automation origins. The origin of automation in the clinical laboratory dates back to the late 1950s, with automation in specimen analysis. Credit for the first automated analysis device is often given to Leonard Skeggs for his continuous-flow analysis device in 1957 (20). However, as progress in analytical automation proceeded throughout the remaining portion of the century, the demands of the clinical laboratory to process specimens at scale became daunting, which led to increasing demands for automation in other areas of the laboratory, such as hematology and microbiology. Additionally, analytic automation created a level of testing accuracy and reliability that was difficult to achieve using human specialists.

Robotic systems have made it possible to test large numbers of patients reliably and accurately and have begun to permeate the laboratory. These systems are available in nearly every service line of the laboratory. However, automation has almost wholly neglected the delivery of specimens and the requirement for preanalytical processing of samples before processing in analyzers. While precision and speed were the primary reasons for the creation of automation in the analysis phase of testing, unfortunately, it has been challenging to justify more significant automation efforts for several reasons:

- Technical considerations
- Costs
- Regulatory requirements

Technical challenges have plagued initial efforts to deliver specimens into and around the laboratory (21). Organizationally, it is challenging to create a laboratory that houses large conveyor systems without the need to shut down the current testing workflow. Additionally, the increasing demand for maintenance creates additional obstacles for the administration and staff of most healthcare-related systems. Historically, analyzer companies have developed offerings that further connect the analyzer to the laboratory by automating some of the initial steps in the analysis process—often taking over much of the preanalytical work performed by the technologist. Increasingly, these systems have become more advanced, to the point of moving specimens throughout the laboratory. However, analyzer companies do not perform this function well, and these systems are often highly bulky and cumbersome to implement in the laboratory. Increasingly, analyzer companies have utilized partnerships to leverage the most recent advances in manufacturing and supply chain management to improve the movement of specimens around the laboratory.

The strategic partnerships between analyzer companies and those specializing in warehouse supply chain are overcoming these challenges. Additionally, new entrants into the robotics portion of the clinical laboratory have reduced the difficulties of implementation. As a result, the technical problems are being overcome quickly and are unlikely to remain for much longer.

Measurement difficulty. The measurement of costs is much more challenging than might first appear. It is not difficult to calculate the costs of reagents and other fixed costs across time. What is more complicated is understanding the "soft" costs of labor. For example, what is the cost if a technologist walks across the laboratory to get some reagents? One could time the staff and then divide that time against the shift costs, but usually, this is difficult and does not account for down time, when technologists are available to work on urgent or high-value specimens. Therefore, since the movement of samples within the clinical laboratory has no calculable cost from a bookkeeping

本书版权归John Wiley & Sons Inc.所有

perspective, it is undervalued. The difficulty of quantifying such tasks leads to a collective imprecision around the actual price associated with functions that we might automate. Generally, where there is imprecision, administrators are at a loss to properly understand the value, leading to an undervaluation of the task. In addition, many technologists perform the opposite calculation, conversely overvaluing every moment of their time, leading to a general mistrust of administration. However, the general point is clear: if tasks are challenging to measure, they will be undervalued by the "bean counters," leading to a poor return on investment (ROI) for automating these tasks.

As financial margins become highly scrutinized and laboratories are being asked to do more work for less compensation, hospitals are becoming much more capable of using economic prediction and bookkeeping models. As a result, the accuracy with which costs may be predicted and evaluated is becoming much higher. Unfortunately, much of medicine is being driven by costs, but the efficiency of laboratory testing is likely to be of benefit as costs are more accurately determined. The value of laboratory automation will be properly calculated, and such automation is very likely to represent much more value for health systems than remaining manual.

The Food and Drug Administration (FDA) is responsible for regulating medical devices. Much of the clinical laboratory consists of a series of medical devices that have been FDA approved or cleared for a specific purpose. However, the movement of generic specimens into and throughout the laboratory is a general-purpose function that is not usually limited to medical needs. These functions are performed equally well in a laboratory or warehouse where goods are delivered. Therefore, manufacturing and supply chain companies that design and create these systems do not have an FDA approval for the movement of clinical specimens of a medical nature. As a result, FDA approval has created a relatively high barrier to entry into the automation space for the clinical laboratory.

Appropriate clearance and marketing will be scrutinized with the emergence of new entrants into the automation market. It is likely that companies seeking to differentiate themselves in a crowded environment will seek FDA approval. Approval by any federal regulatory body has persistently generated returns for profitable ventures, which is likely to continue. It seems fairly clear that FDA approval for these automation systems will proceed and ultimately make the laboratory much more effective and efficient.

Laboratory Consultation

The laboratory's responsibility to interpret test results for the patient is an opportunity that could be a significant advantage for the field. For decades, hospitals have relegated pathology to the "basement" despite the high impact of diagnostic information (2, 22). As a result, the pathology department gets very little credit in the patient's mind. Now, that is all about to change. It will become evident to the patient who performs the appropriate test, and they (the pathologist) should be relied upon to understand and interpret it. This transparency of the value of pathology will create a very different dynamic between the clinical and laboratory teams. No longer will the clinical team be relied upon to interpret test results and recommend therapy; instead, the clinical team will likely limit their focus to management and therapy decisions.

Laboratory consultation efforts have shown great promise in the past. However, several factors have delayed them, including limited desire to consult with laboratory experts by clinicians, payment structures that incentivize additional testing, and limited access to clinical information pertinent to consultations. Increasingly, these barriers are being torn down.

Physicians have become increasingly interested in subspecializing during medical education, resulting in fewer generalist providers (22–25). The drive toward subspecialization has resulted in a shortage of generalist providers across rural and urban areas of the United States. The need for generalists has become so great that some educational initiatives have started to reduce the required duration of medical education to entice more students to these career fields (26). Additionally, state legislators have in recent years expanded the role of midlevel practitioners to include additional responsibilities traditionally held by clinicians. These initiatives by lawmakers are understandable, as these providers are intended to provide higher levels of standardization for patient care and to allow access where current barriers now exist, such as geographic limitations. Midlevel providers have a relatively broad-based solid educational model that focuses on standardized responses to care and an algorithm approach to testing. Their training includes clinical care and didactic education sessions. Understandably, the curriculum is not as lengthy as physician training, resulting in some potential limitations such as limited clinical exposure and potentially limited laboratory knowledge.

Medical cost concerns. The public has increasingly been interested in the reduction of medical costs (27, 28). Healthcare costs have consistently outpaced inflation in the previous 3 decades, and this trend is unlikely to abate. As a result, public expenditures for healthcare have begun to escalate beyond previously predicted levels and have garnered attention from the legislature and the public. Much of the blame for rising healthcare costs has been placed on laboratory testing, as these costs have increased precipitously, both in terms of cost per test and the volume of tests.

As the difficulty in interpreting and ordering laboratory tests has risen, clinicians are increasingly unable to

本书版权归John Wiley & Sons Inc.所有

order and interpret tests promptly and correctly. In addition, clinicians have increasing constraints on their time, most notably, the rapidly increasing number of treatments available for patients. Other limitations exist, including political and financial concerns for patients and social problems related to effective treatment. It is not for us to discuss all of the time constraints for clinicians, but rather to articulate that many competing factors have led to difficulty and continued challenges for clinicians in the laboratory space.

The laboratory must fill the vacuum left by the inability to correctly interpret and order laboratory testing. Given this responsibility, the pathology team can no longer rely upon anonymity, thus making the job much harder but higher profile. The laboratorian must be available to answer questions and discuss with patients what their interpretation means within the clinical context of the patient's history and other diagnostic assessments. Therefore, understanding the patient's history and entire picture will be critical. In addition, knowing how to use the electronic medical records and reading charts will be necessary to succeed and thrive in the future. Laboratory consultations can take many forms, one of the most popular being the diagnostic management team (DMT). DMTs are teams of diagnostic experts, usually pathologists as well as other laboratory specialists, who review clinical cases for the purposes of optimizing test selection and interpretation for the patient. They have been shown to improve test selection and are cost-effective structures for the optimization of tests in the hospital and outpatient settings. Given the cost-consciousness of hospitals, the current political climate focused on improving healthcare for an aging population, and the COVID-19 response resulting in reduced elective procedures, health systems are focused on controlling costs as well as they can. Therefore, laboratory consultation services will play an increasingly important role in the health systems of the future.

Remote Ready

Pathology has a somewhat rare opportunity among medical professions to embrace a remote working environment. Much of the analytical and interpersonal work done by attending physicians in pathology is able to be done remotely. Pathology informatics, in particular, can essentially be performed remotely.

Medicine is, and always has been, in a race for the best talent available. As a result, many workers enjoy the luxuries of a remote working environment. In addition, pathology is uniquely suited for remote engagement relative to many other medical specialties, resulting in a likely infusion of interest from trainees attracted by remote work. Therefore, it could be advantageous to embrace this remote working capability in the field.

Additionally, when there is a drastic difference between the opportunities at one institution and those at another, the institution with the best offer package almost always can attract the superior candidate. Therefore, institutions must maintain the most flexibility possible to allow new faculty and staff to work remotely, in order to attract the best and brightest employees. Conversely, if departments remain dogmatic in their approach, the most valuable workers will look elsewhere for employment, and departments will have an increasingly difficult time assembling impactful teams.

Unfortunately, institutions will increasingly need to be wary of challenges with isolation. During the growth phase of remote working arrangements, it is likely that loneliness and depression will affect teams. Therefore, pathology departments would do well to maintain strong connections with faculty and staff working remotely, either entirely or partially.

Despite challenges, remote working arrangements are likely to persist because many people enjoy them. Institutions that embrace the new working realities will attract higher-caliber candidates and are more likely to assemble solid and effective teams.

Laboratory Principles To Live By

As hospitals and laboratories recover from the cumulative shocks of the COVID-19 pandemic, several general principles may be helpful for any pathology department. We believe that these principles will serve the field of pathology well in the coming years.

Accuracy and Reliability

Laboratory departments need to provide the right information for the correct patient at the appropriate time to our clinical colleagues. In addition, changes to workflow, test menu, test systems, procedures, faculty, and staff need to maintain or improve the reliability of the laboratory.

Clinical physicians have increasingly become dependent on the clinical laboratory to assist with or even make diagnostic decisions. As a result, improvements in laboratory medicine and other technologies with higher sensitivity and specificity for diagnosing disease have become increasingly valued in clinical practice. It has been estimated that roughly 70% of clinical diagnoses are made utilizing laboratory values (2). Given the increasing complexity of diseases and their equally complex management, the trend of using more and more laboratory tests will continue. Therefore, as clinical practice relies more heavily on the laboratory, the laboratory must maintain a high standard of accuracy and reliability for the tests performed to continue our position as a highly accurate and reliable source of valued patient information.

本书版权归John Wiley & Sons Inc.所有

Scalability

The inability to increase or decrease production consistently creates hurdles to effectiveness and artificially restrains the overhead costs of the laboratory. For example, during the COVID-19 pandemic, patients feared going to the hospital because they did not want to risk contracting the disease. Additionally, in attempts to "flatten the curve," hospital administrators reduced clinical departments, nonemergency surgical interventions, and support infrastructure drastically to minimize costs and stave off financial failure. While potentially not as negatively impacted as some departments, the laboratory nevertheless saw reductions in testing by an average of 60% and billions of dollars of reduced revenue (29). Fortunately, the federal government assisted small businesses via temporary financial aid to businesses, workers, and families (30).

Laboratory professionals and the departments they serve should attempt to be able to both scale up and scale down production in the face of challenges. Of course, limitations to scalability exist, such as sunk costs and maintenance overhead. However, an attempt to remain flexible in our processes will reduce labor operational costs, specifically within workflow requirements.

On the opposite side of the equation, laboratories need to scale up operations quickly, as necessary. Increasing profitability by outreach programs increases local demand, and improved efficiency can significantly improve laboratory profitability. However, hurdles to increasing scale are often challenging to isolate. For example, contracts with suppliers and workforce limitations can often limit growth. Limiting these restrictions, while challenging at the moment because of the advantages they represent, can optimize the department for a change in the long term and reduce risks.

Coordination

The laboratory workforce, service lines, and test systems should work in concert so that specimens and information can be freely shared throughout the laboratory, across the laboratory information service software, and with providers.

Cross training of laboratory professionals is difficult and time-consuming. Learning and being proficient in multiple roles will decrease the effectiveness of the lab testing personnel proportional to the number of roles and responsibilities they have. Additionally, laboratory professionals prefer to specialize in a limited number of systems and limit task switching because it makes their jobs easier and more straightforward, and theoretically, they become more efficient (31). While it is true that cross training can decrease efficiency, the benefits of a coordinated workforce vastly outweigh the costs. Success will depend on the level/complexity of cross training and how often the staff member is called upon to cover another area. Extended periods of time between coverage of an area may lead to a loss of skills required for accuracy and competence.

Conversely, it is preferable to increase the number of roles and responsibilities for each team member because it introduces novelty to staff working conditions, increases the robustness of procedures and policies, and increases laboratory flexibility in staffing.

Laboratory professionals can become bored with repetitive tasks over a long period. Allowing cross training introduces interesting new challenges that aid in job satisfaction.

Exposing procedures and policies to the scrutiny of more staff allows for a broader assessment of the usefulness of these policies and procedures. Allowing more individuals to review and comment on these documents helps remove many errors. Periodic reviews and updates to these policies and practices will improve laboratory performance.

Increasing the number of staff available to perform various activities makes scheduling far easier. More importantly, however, when significant work shifts occur, such as the increasing need for COVID-19 testing, teams can "spring into action" and assist in varying areas.

Flexibility

Laboratories focusing on flexibility enjoy two distinct advantages over less flexible ones. Specifically, the ability of workers to perform different tasks was highly desirable during the COVID-19 pandemic, when many analysis techniques were attempted, some which had great success and others which were dismal failures, with so much conflicting information available during the pandemic that it was often difficult to know what testing should be performed. Technologists who could flexibly move from one test system to another were highly valued.

Additionally, laboratories that maintain flexible or interoperable architecture prioritize systems that may be slightly less efficient but have more capabilities. Typically, when comparing systems, it is advantageous to optimize performance against specific variables such as speed or run costs. However, departments that prioritize robustly interoperable systems appear to be more resilient to complex challenges and more able to respond to the changing clinical landscape.

SUMMARY

Pathology has evolved in the last 150 years from being almost nonexistent to becoming one of the most essential parts of the healthcare system. Laboratory tests inform clinicians by helping diagnose and track the performance of therapies for patients. With the ever-increasing number and variety of tests, appropriate ordering of tests and interpretation of results become difficult for clinicians, leading to opportunities for consultation services for pathologists,

本书版权归John Wiley & Sons Inc.所有

as well as other laboratory specialists. Additionally, the ability to increase operational performance while decreasing labor costs has significant implications for the future of automation in the laboratory. Finally, as the number of tests increases, the clinical and operational insights determined with this information increase rapidly, and pathology departments will use machine learning algorithms to glean understanding, all while working from home or elsewhere away from the office or hospital. With advances in consultation services, work arrangements, automation, and machine learning, the future of pathology is very exciting, and the field is poised to lead medicine to a bright future.

KEY POINTS

- The impact of clinical pathology has evolved in the last 150 years from almost nonexistent to being one of the most essential parts of the healthcare system.
- Laboratory tests inform clinicians by helping diagnose and track the performance of therapies for patients.
- Laboratory consultation services will grow in importance as clinicians need assistance with appropriate ordering and interpretation of laboratory tests.
- Operational performance improvements with decreasing labor costs will be achieved through laboratory automation efforts.
- Remote working arrangements will likely lead to a happier workforce, but disadvantages need to be overcome.
- Increasing information from the clinical laboratory will lead to the use of machine learning algorithms to assist healthcare systems in achieving improved performance.
- The future of clinical pathology is very exciting, and the field is poised to lead medicine into a bright future.

GLOSSARY

Academic medical centers Hospitals associated with medical schools.

Anatomic pathology Branch of pathology that deals with gross and microscopic diagnosis of surgical and autopsy tissues, as opposed to clinical pathology, which deals with laboratory testing.

Clinical laboratory consultation Providing advice on test strategy and interpretation of test results.

Clinical pathology Branch of pathology that deals with laboratory testing, as opposed to anatomic pathology, which deals with gross and microscopic diagnosis of surgical and autopsy tissues.

Current procedural terminology codes Systematic five-digit codes defining medical procedures or services and required for billing purposes.

Deep learning Subcategory of machine learning wherein the functions used to map inputs to outputs are of a specific category known as neural networks.

Laboratory medicine Virtually synonymous with "clinical pathology," with the exception that the term is more often used when referring to academic medical centers as opposed to community hospitals.

Laboratory utilization The frequency with which laboratory tests are ordered and performed.

Point-of-care testing Testing usually conducted by nontechnical personnel at the bedside, in the clinic, or in the home.

Reinforcement learning Subtype of machine learning which may use neural networks (in the case of deep reinforcement learning) but does not have to and is itself defined by the selection of model inputs and outputs.

Wrong blood in tube Medical system event in which a patient specimen is either mislabeled or collected incorrectly, resulting in the incorrect patient specimen being delivered or processed.

REFERENCES

1. **Fletcher WM**. 1929. Norman Lockner lecture on medical research: the tree and the fruit. *BMJ* **2**:993–996.

2. **Becich MJ**. 2000. Information management: moving from test results to clinical information. *Clin Leadersh Manag Rev* **14**:296–300.

3. **Benson ES**. 1981. Ward Burdick Award lecture. Laboratory medicine in the United States: the dream and the reality. *Am J Clin Pathol* **76**:1–7.

4. **Burke MD**. 1994. Clinical pathology residency training. The need for reform. *Arch Pathol Lab Med* **118**:489–490.

5. **Bureau of Labor Statistics**. 2021. Occupational outlook handbook.https://www.bls.gov/ooh/healthcare/medical-and-clinical-laboratory-technologists-and-technicians.htm#tab-6. Accessed 11 December 2021.

6. **Garcia E, Kundu I, Fong K**. 2021. American Society for Clinical Pathology's 2019 wage survey of medical laboratories in the United States. *Am J Clin Pathol* **155**:649–673.

7. **Garcia E, Kundu I, Kelly M, Soles R**. 2022. The American Society for Clinical Pathology 2020 vacancy survey of medical laboratories in the United States. *Am J Clin Pathol* **157**:874–889.

8. **Salmi L, Blease C, Hägglund M, Walker J, DesRoches CM**. 2021. US policy requires immediate release of records to patients. *BMJ* **372**:n426.

9. **Bell SK, Mejilla R, Anselmo M, Darer JD, Elmore JG, Leveille S, Ngo L, Ralston JD, Delbanco T, Walker J**. 2017. When doctors share visit notes with patients: a study of patient and doctor perceptions of documentation errors, safety opportunities and the patient-doctor relationship. *BMJ Qual Saf* **26**:262–270.

10. **Wright E, Darer J, Tang X, Thompson J, Tusing L, Fossa A, Delbanco T, Ngo L, Walker J**. 2015. Sharing physician notes through an electronic portal is associated with improved medication adherence: quasi-experimental study. *J Med Internet Res* **17**:e226.

本书版权归John Wiley & Sons Inc.所有

11. DesRoches CM, Bell SK, Dong Z, Elmore J, Fernandez L, Fitzgerald P, Liao JM, Payne TH, Delbanco T, Walker J. 2019. Patients managing medications and reading their visit notes: a survey of OpenNotes participants. *Ann Intern Med* **171**:69–71.

12. Delbanco T, Walker J, Bell SK, Darer JD, Elmore JG, Farag N, Feldman HJ, Mejilla R, Ngo L, Ralston JD, Ross SE, Trivedi N, Vodicka E, Leveille SG. 2012. Inviting patients to read their doctors' notes: a quasi-experimental study and a look ahead. *Ann Intern Med* **157**:461–470.

13. Blumenthal D, Abrams MK. 2019. Ready or not, we live in an age of health information transparency. *Ann Intern Med* **171**:64–65.

14. Davis Giardina T, Singh H. 2011. Should patients get direct access to their laboratory test results? An answer with many questions. *JAMA* **306**:2502–2503.

15. Wang B, Liu Y, Qian J, Parker SK. 2021. Achieving effective remote working during the COVID-19 pandemic: a work design perspective. *Appl Psychol* **70**:16–59.

16. Yang L, Holtz D, Jaffe S, Suri S, Sinha S, Weston J, Joyce C, Shah N, Sherman K, Hecht B, Teevan J. 2022. The effects of remote work on collaboration among information workers. *Nat Hum Behav* **6**:43–54.

17. Koski E, Murphy J. 2021. AI in healthcare. *Stud Health Technol Inform* **284**:295–299.

18. Mistry NS, Koyner JL. 2021. Artificial intelligence in acute kidney injury: from static to dynamic models. *Adv Chronic Kidney Dis* **28**:74–82.

19. Zdolsek G, Chen Y, Bögl HP, Wang C, Woisetschläger M, Schilcher J. 2021. Deep neural networks with promising diagnostic accuracy for the classification of atypical femoral fractures. *Acta Orthop* **92**:394–400.

20. Skeggs LT Jr. 1957. An automatic method for colorimetric analysis. *Am J Clin Pathol* **28**(3_ts):311–322.

21. Genzen JR, Burnham CD, Felder RA, Hawker CD, Lippi G, Peck Palmer OM. 2018. Challenges and opportunities in implementing total laboratory automation. *Clin Chem* **64**:259–264.

22. Verna R, Velazquez AB, Laposata M. 2019. Reducing diagnostic errors worldwide through diagnostic management teams. *Ann Lab Med* **39**:121–124.

23. Rajendran R, Salazar JH, Seymour RL, Laposata M, Zahner CJ. 2021. Overutilization and underutilization of autoantibody tests in patients with suspected autoimmune disorders. *Diagnosis (Berl)* **8**:497–503.

24. Zhang X, Lin D, Pforsich H, Lin VW. 2020. Physician workforce in the United States of America: forecasting nationwide shortages. *Hum Resour Health* **18**:8.

25. Sullivan RB, Watanabe M, Whitcomb ME, Kindig DA. 1996. The evolution of divergences in physician supply policy in Canada and the United States. *JAMA* **276**:704–709.

26. Jones BG, Berk SL. 2016. The family medicine accelerated track at Texas Tech University Health Sciences Center. *Tex Med* **112**:62–67.

27. Speer M, McCullough JM, Fielding JE, Faustino E, Teutsch SM. 2020. Excess medical care spending: the categories, magnitude, and opportunity costs of wasteful spending in the United States. *Am J Public Health* **110**:1743–1748.

28. Saltiel M. 2018. Hyperinflation—introduction. *J Pharm Pract* **31**:369.

29. Michel RL. 4 May 2020. COVID-19 triggers a cash flow crash at clinical labs totaling US $5.2 billion in past seven weeks; many labs are at brink of financial collapse. *Dark Daily*.

30. 116th Congress. 27 March 2020. Public Law 116–136. Coronavirus Aid, Relief, and Economic Security Act.

31. Kim YJ, Kim G, Kim S, Jung D, Park M. 2021. Designing optimizing procedures for task switching to ensure efficiency in the hospital laboratory. *Sci Rep* **11**:12717.

本书版权归John Wiley & Sons Inc.所有

本书版权归John Wiley & Sons Inc.所有

XII

Pandemics and Healthcare Institutions

(SECTION EDITOR: **Deirdre L. Church**)

50 Epidemics and Pandemics: Lessons from the Past, Concerns for the Future
Charles S. Bryan

51 One Health in Pandemic Planning, Prevention, and Response
Craig Stephen

52 Pandemic Planning: Roles of Clinical and Public Health Laboratories
Robert T. Ball, Jr., Joseph F. John, Jr., and Michael G. Schmidt

53 Laboratory Preparedness
Deirdre Church

本书版权归John Wiley & Sons Inc.所有

本书版权归John Wiley & Sons Inc.所有

50

Introduction
Some Basics of Epidemiology
The Importance of Zoonoses
Epidemics and Pandemics as Four-Act Plays
Act One: Progressive Revelation • Act Two: Management of Randomness • Act Three: Negotiation of a Public Response • Act Four: Subsidence and Retrospection
Lessons from Selected Epidemics and Pandemics from Antiquity through HIV/AIDS
Epidemics of Antiquity • Plague • Smallpox • Yellow Fever • Cholera • Influenza • HIV/AIDS
Coronaviruses and COVID-19
Coronaviruses • Severe Acute Respiratory Syndrome • Middle East Respiratory Syndrome • COVID-19 as a Four-Act Play
The Anthropocene and Future Epidemics and Pandemics
The Anthropocene Epoch • Threats Posed by Currently Known Infectious Agents • Potential Threats from Novel Pathogens
Roles of Laboratories
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch50.

Epidemics and Pandemics: Lessons from the Past, Concerns for the Future

Charles S. Bryan

OBJECTIVES

To define terms commonly used by epidemiologists and public health officials, including "R_0," the basic reproduction number

To describe the usual sequence of events resulting from epidemics and pandemics

To trace the development of insights into the recognition and management of epidemics and pandemics, from antiquity through COVID-19

To explain the need for global cooperation in public health

To discuss future threats caused by presently known agents or by novel agents, which might occur naturally or result from human ingenuity (bioterrorism)

To appreciate the importance of infectious diseases in the context of the Anthropocene Epoch

To identify the roles of laboratories in the recognition of, and coordinated response to, epidemic and pandemic infectious disease

> *Humanity has but three great enemies: fever, famine and war: of these by far the greatest, by far the most terrible, is fever.*
>
> William Osler, 1896

> *There must be a very different civilization or there will be no civilization at all.*
>
> William Osler, 1919

Epidemics and pandemics are unintended consequences of civilization. Expanding human populations, encroachment on the animate environment, international travel, and the potential for bioterrorism heighten the risk of epidemics and pandemics in the Anthropocene, the proposed geologic epoch in which we now live. This chapter pertains to lessons learned from pandemics of previous centuries and sometimes forgotten, lessons from the first 2 years of the COVID-19 (coronavirus disease 2019) pandemic, and how we might brace for a future in which infectious diseases will increasingly threaten humankind.

本书版权归John Wiley & Sons Inc.所有

Some Basics of Epidemiology

"Epidemiology" from its Greek roots denotes "the study of what is upon the people." Skill sets now include higher mathematics and genome-based molecular biology, but meticulous data collection ("shoe-leather epidemiology") remains essential. Here we use concepts familiar to epidemiologists (see the glossary), beginning with the formula for infection and the epidemiologic triad and a relatively new term, the basic reproduction number (R_0, pronounced "*R*-naught").

The formula for infection expresses the idea that the likelihood of infection depends on the infectivity and virulence of the infectious agent, the inoculum size (the number of microorganisms or virus particles), and host resistance to infection. The epidemiologic triad expresses the idea that an infectious agent must have a reservoir, a means of transmission (which can be direct, as by contact or inhalation of droplet nuclei, or indirect, as through a vector or vehicle), and a susceptible host.

The basic reproduction number (R_0) is an imprecise summary parameter used to predict the spread of an infectious agent in a previously unexposed population. It denotes the average number of secondary cases resulting from a single infected person, assuming that exposed persons have no immunity. For example, if the R_0 value is 2, the first infected person (index case) will infect two additional persons; those two will infect four persons, who will infect 16 persons, and so on. An R_0 value greater than 1 signifies that an epidemic will continue; an R_0 value less than 1 indicates that an epidemic will subside. Complexities inherent to the concept of R_0 exceed the scope of this brief account.

The terms "cluster," "outbreak," "endemic" (from the Greek, "among the people"), "hyperendemic," "epidemic" ("upon the people"), and "pandemic" ("throughout the people") are somewhat arbitrary (see the glossary). Descriptive epidemiology is used to characterize initial cases (reported or identified by public health surveillance), to determine the natural history of a disease, and to construct an epidemic curve. Analytic epidemiology engages the search for causes and effects. Applied epidemiology entails implementation of control measures. Epidemiology is thus the cornerstone to the recognition and management of infectious diseases with pandemic potential.

The Importance of Zoonoses

COVID-19 and monkeypox underscore the importance of zoonoses (diseases that spread to humans from nonhuman animals), which account for about 60% of all infectious diseases, up to 70% of emerging infectious diseases, and nearly 90% of human diseases caused by RNA viruses. Biologic diversity, adaptability, high mutation rates, and ease of transmission make RNA viruses the most likely candidate agents for future pandemics. Examples of such RNA viruses include influenza viruses, coronaviruses (the agents of severe acute respiratory syndrome [SARS], Middle East respiratory syndrome [MERS], and COVID-19), and the viruses that cause chikungunya, dengue, Ebola, and West Nile fever. One Health strategies (see chapter 51) address the human-animal-environment interface responsible for these clear and present dangers to humankind (1–3).

Epidemics and Pandemics as Four-Act Plays

The historian Charles Rosenberg proposed in 1989 that epidemics (or pandemics) characteristically unfold as four-act plays, as follows (4).

Act One: Progressive Revelation

Healthcare providers identify out-of-the-ordinary cases. These may take the form of a known disease (such as influenza A) or a previously undescribed syndrome of unknown cause (such as HIV/AIDS, in 1981). Public officials may deny or downplay the problem, since control measures would disrupt the economy. Cases accumulate.

Act Two: Management of Randomness

People ask who is getting the disease and why. Risk factors for disease and death, and the relative risks among subsets of the population, become apparent. Individuals often minimize their own risks. Pressure mounts on scientists for answers and public officials for action. Conspiracy theories arise—surely, someone is to blame. Public opinion may become polarized.

Act Three: Negotiation of a Public Response

The need for government intervention is now clear, but practical and ethical dilemmas arise. Which interventions will work and at what cost? Should the more affluent and privileged members of society, who have better access to avoidance strategies, pay to protect the less fortunate? What are the risks to caregivers? To what extent, if any, can governments mandate vaccines and other measures?

Act Four: Subsidence and Retrospection

Fewer cases occur. The disease disappears or becomes endemic, a risk of daily living. Scientists, health officials, historians, ethicists, public intellectuals, and others weigh in on why the epidemic occurred, what it meant, and what it portends for the future.

Each epidemic or pandemic writes its own playbook. The reader may find it useful to keep these acts in mind as we survey plagues from previous centuries before applying Rosenberg's dramaturgic model to the first 2 years of the COVID-19 pandemic.

Lessons from Selected Epidemics and Pandemics from Antiquity through HIV/AIDS

Epidemics of Antiquity

From antiquity came the benefits of hygiene and simple public health measures and an understanding of the importance of zoonoses and the phenomenon of active immunity.

本书版权归John Wiley & Sons Inc.所有

Other lessons include those regarding conspiracy theories, xenophobia, biologic warfare, risks to caregivers, social disruption, and damage to the fabric of democracy.

Soap originated in ancient China and Mesopotamia. It receives four mentions in the Hebrew Bible, which also stipulates social distancing (isolation) for persons with leprosy (a term not confined to what we now call Hansen's disease).

Ancient civilizations of China, the Nile Valley, and Babylon knew the relationship between animals and human diseases (zoonoses). Biologic warfare possibly dates to the 14th century BCE, when the Hittites, it is suggested, gave tularemia-infected animals to their Middle Eastern neighbors. The Book of Leviticus forbade Jews from eating pork (trichinosis), hares (tularemia), camels (echinococcosis), bivalve shellfish (hepatitis A), reptiles (salmonellosis), bats (rabies and, more recently, Ebola and coronavirus diseases), and certain other animals.

Low population densities made epidemics rare during antiquity. The Greek writers known collectively as Hippocrates wrote seven treatises on "epidemics," but the diseases they described were endemic, not epidemic in the modern sense. They recognized the effects of seasonality and climate on disease incidence.

The historian Thucydides described the Plague of Athens, which began in 430 BCE during the Peloponnesian War against Sparta and its allies. Refugees seeking protection within the city walls swarmed into Athens, compromising sanitation and facilitating spread of the mysterious pathogen. The disease killed an estimated 25 to 33% of the population, including the great leader Pericles. Many accused Spartans of poisoning the water supply. Authorities quarreled among themselves. Attitudes hardened toward foreigners, defined as anyone not born in Athens. Caregivers experienced high mortality, but survivors did not get the disease a second time. The plague marked a downturn in Athenian democracy that culminated a century later when the people accepted a dictator-king. Thucydides wrote, "The people were conquered by the evil."

Plague

From plague, humans learned about the causative role of international travel and commerce and about the preventative value of quarantine, isolation, and perhaps face masks; it also gave rise to boards of health and immigration policies, the use of hospitals for therapeutic purposes, and the advent of descriptive epidemiology and taught the significance of new strains (biovars) of an old pathogen, *Yersinia pestis*. Other lessons include those regarding conspiracy theories, persecution of minorities, social upheavals, and, more recently, death threats against the eminent public health official who founded what is now the U.S. National Institutes of Health (NIH).

Y. pestis finds its reservoir in rodents; humans acquire it from fleas or, less commonly, by inhalation. There have been at least three pandemics: the Justinian plague of the 6th century, which arguably contributed to the fall of the Roman Empire; the Black Death, which began during the 14th century; and the modern plague, which began in China during the 1850s with the emergence of *Y. pestis* strains known as biovar orientalis.

Bubonic plague, its name derived from the swollen and painful lymph nodes (buboes), is the usual form of the disease and carries a case fatality rate of about 50%. Data from the Black Death suggest an R_0 value of 1.6 to 1.9, but the R_0 was between 5 and 7 during the peak of a 2017 plague epidemic in Madagascar. Pneumonic plague, whose agent is transmitted by aerosol and hence a potential agent for germ warfare, is almost uniformly fatal without treatment and has an estimated R_0 value of 2.8 to 3.8.

The Black Death began in Asia and reached the Crimean port of Kaffa (now Feodosia) in 1346 by way of a network of trade routes known as the Silk Road. Invading Mongols allegedly threw plague-infected corpses over the city walls. From Kaffa ships, plague spread throughout the Mediterranean Basin and the Middle East and into Europe, where it killed an estimated one-quarter to one-third of the population.

Venetians initiated quarantine, the term denoting the 40 days (*quaranta giorni*) ships had to wait in harbor to ensure the absence of plague. They also established a Committee of Three "to consider diligently all possible ways to preserve public health and avoid corruption of the environment," a prototype for boards of health. Sanitary cordons (lines of armed guards) regulated international travel, notably along the border between the Habsburg and Ottoman empires.

Medical texts began to appear in vernacular languages instead of Latin. Hospitals, previously used mainly to isolate persons with leprosy (*lazarettos*), assumed a therapeutic role especially for drainage of buboes. Surgeons gained prestige by their willingness to be thus exposed. The French surgeon Guy de Chauliac (1300 to 1368) wrote a code of conduct whereby the doctor should be "well mannered, bold in many ways . . . kindhearted to his colleagues, wise in his prognostications . . . chaste, sober, compassionate, and merciful . . . [and avoid being] covetous, [or] grasping in money matters."

The leading conspiracy theory alleged that Jews had poisoned wells. Anti-Jewish hysteria led to massacres, destructions of entire towns, and eastward displacement of Jewish populations from Spain and France. The Paris medical faculty issued a more scientific explanation, asserting "the distant and first cause of this pestilence" to have been a conjunction of Mars, Jupiter, and Saturn at 1:00 p.m. on 20 March 1345. Cases of plague attributed to the Black Death occurred in Western Europe as late as 1815 and Eastern Europe as late as 1879.

Wealthier persons, including many physicians, fled to the countryside. Cities contracted with "plague doctors"

本书版权归John Wiley & Sons Inc.所有

who, beginning in 17th-century Paris, donned costumes with bird-like beak masks. They stuffed the beaks with herbs, spices, and dried flowers to ward off odors and prevent transmission by "miasmas." A London haberdasher named John Graunt (1620 to 1674) tabulated data on plague in the later editions of his *Natural and Political Observations upon the Bills of Mortality* (published between 1661 and 1676), making him the acknowledged father of descriptive epidemiology.

In 1894, the Japanese physician-bacteriologist Shibasaburo Kitasato (1856 to 1931) and his Swiss-French counterpart, Alexandre Yersin (1863 to 1894), isolated the causative bacillus in Hong Kong within days of each other.

In 1899, ships from Hong Kong brought plague to San Francisco. Joseph J. Kinyoun (1860 to 1919), in whose laboratory the NIH originated, was the newly appointed quarantine officer. Kinyoun proposed measures to confine the outbreak to Chinatown. Governor Henry Gage and others publicly ridiculed Kinyoun, who received many death threats. *Y. pestis* became established in rodents in the western United States, where cases still occur each year.

The Malaysian-Chinese epidemiologist Wu Lien Teh (1879 to 1960) made the 1910 epidemic in Manchuria memorable for effective control measures. Wu designed a face mask consisting of absorbent cotton sandwiched between layers of cloth and gauze. His face mask became a model for surgical masks, which became in turn a model for N95 masks. Wu won fame as "the plague doctor of China."

Global warming may generate new plague epidemics by enhancing flea transmission in warm, sparsely populated areas.

Smallpox

From smallpox came an appreciation of the value of immunization (vaccination), the application of higher mathematics to descriptive epidemiology, and the realization that science combined with reason might eradicate (remove entirely) an existential threat to humankind. Other consequences include antivaccination movements sometimes bordering on frenzy.

The last naturally occurring case of smallpox occurred in a hospital cook in Somalia in 1977, less than 20 years after the World Health Assembly launched its eradication initiative. Making smallpox eradication possible were (i) the absence of an animal reservoir, (ii) a lack of transmission by asymptomatic carriers, (iii) the availability of an effective vaccine, and (iv) low mutation rates in the *Variola* virus genome. The World Health Organization (WHO) monitors the two locations in which the smallpox virus is now stored—the Centers for Disease Control and Prevention (CDC) in Atlanta, GA, and the VECTOR Institute in Koltsovo, Russia—and maintains a stockpile of vaccine at its headquarters in Switzerland.

The more common and severe form of smallpox had a case fatality rate of about 30%, but the rare hemorrhagic form was uniformly fatal. The R_0 value for smallpox was between 3.5 and 6.

The highest pandemic-related mortality in recorded history followed European colonization (invasion) of the Western Hemisphere. Indigenous peoples had no immunity to smallpox and other European diseases, notably measles (which has an R_0 value of 16 to 18). Mortality rates approximated 90% in some populations, enabling Spanish conquistadors to destroy the Aztec and Inca civilizations and other Europeans to colonize North America. When indigenous tribes protested English settlements in present-day Massachusetts, the Reverend Increase Mather wrote in 1633, "God ended the controversy by sending the smallpox among the Indians."

Active immunization initially took the form of variolation (also called inoculation), which involved introducing material from a smallpox pustule into the skin or mucous membranes of an uninfected individual. This usually resulted in a mild case of smallpox and permanent immunity, but it occasionally caused severe disease and death. Variolation was therefore a calculated risk. It was while building an argument for variolation that, in 1766, the Swiss mathematician and physicist Daniel Bernoulli (1700 to 1782) introduced higher mathematics including calculus to descriptive epidemiology.

North American colonists and British armed forces gave smallpox-infected blankets to indigenous peoples during the wars of the late 18th century. Resistance to variolation was widespread when, in February 1776, George Washington ordered variolation for his beleaguered troops at Valley Forge. The troops endorsed the idea that the greater public good sometimes transcends small risks to individuals. Washington's decision became "the shot that won the Revolutionary War."

The English general practitioner Edward Jenner (1749 to 1823) introduced a safer alternative: "vaccination," a term he coined from "vaccinia" (cowpox). Jenner showed by experiment what dairymaids had known for years: they seldom if ever got smallpox after experiencing pustules on their hands (cowpox) from milking. Jenner took cowpox pus from a dairymaid named Sarah Nelmes, inoculated it into 8-year-old James Phipps, and showed the impossibility of giving smallpox to Phipps despite repeated inoculations. Jenner self-published his observations after the Royal Society rejected his manuscript.

Objections to vaccination were almost immediate and for reasons that reverberate today. Parents railed against injecting foreign material into their children. Some clergymen demonized it as "un-Christian." Others viewed compulsory vaccination as infringement on personal liberty, or simply distrusted medicine and science. Antivaccination leagues formed in England and the United States during the second half of the 19th century after some governments made vaccination mandatory. In 1905, the U.S.

本书版权归John Wiley & Sons Inc.所有

Supreme Court, in *Jacobson v. Massachusetts*, upheld the authority of states to enforce compulsory vaccination, articulating that individual liberty is not absolute.

It is unfortunate that the first vaccine was one of the least safe. Researchers have developed safer smallpox vaccines, but efficacy data will not be forthcoming unless smallpox recurs because of laboratory accident or bioterrorism.

Yellow Fever

From yellow fever came the realization that epidemic disease could be controlled by removing an insect vector. Other lessons include those regarding polarization of opinion between physicians and laypersons and harms resulting from treatments based on insufficient data.

Yellow fever is a vaccine-preventable hemorrhagic fever caused by a mosquito-transmitted RNA virus. *Aedes aegypti*, a short-winged household mosquito that breeds in standing water, transmits "urban" yellow fever, the form of the disease responsible for large epidemics. The case fatality rate for yellow fever averages 20 to 50%. The R_0 value for epidemic yellow fever averages about 5 but is highly variable.

Dutch slave traders brought yellow fever to the Western Hemisphere during the 1640s. Epidemics terrorized North American seaports during the 18th and 19th centuries. Physicians and public officials often denied the first cases, since an epidemic would cripple commerce. Nobody knew which control measures were likely to be effective.

The 1793 Philadelphia epidemic pitted "contagionists," who wanted to quarantine all incoming ships, against "anticontagionists," who wanted better sanitation to control environmental factors. Most laypersons were contagionists; most physicians and health officials were anticontagionists. Benjamin Rush (1746 to 1817), the young nation's most famous doctor, stayed in town to treat the sick while others fled. Rush concluded from scanty data that bloodletting and other "heroic" therapies lowered mortality. He generalized this recommendation to other febrile diseases, claiming they resulted from "irregular convulsive action of the blood vessels." Rush's influence resulted in numerous deaths in the United States between 1793 and the 1830s, when enthusiasm for bloodletting began to decline.

Tree hole-breeding mosquitoes in forest canopies perpetuate the virus and cause sporadic cases of "jungle" (sylvatic) yellow fever. Global warming will expand the range of *A. aegypti*, increasing the risk of yellow fever and other diseases caused by RNA viruses such as chikungunya, dengue, and Zika virus disease.

Cholera

From cholera came the birth of analytic epidemiology to guide control measures, the origin of international networks of public health officials, and the first identification of the microbial cause of a pandemic disease. Other lessons include the importance of clean drinking water.

The cholera toxin causes profuse watery diarrhea with case fatality rates above 50% without aggressive fluid replacement. Cholera probably existed in the Ganges River delta for centuries before the first of seven pandemics occurred in 1817, a consequence of trade, warfare, and urban crowding. Some alleged that physicians had poisoned wells to provide corpses for experiments. Others alleged that public officials caused it to thin out poor neighborhoods where the unemployed caused trouble. Still others blamed religious pilgrimages, and anti-Asian sentiment grew in Europe. Debates between "contagionists" and "anticontagionists" resembled those that occurred with yellow fever. Ideas about causation centered on airborne "miasmas." The R_0 value for the second cholera pandemic (1829 to 1837) was about 16; in more recent experiences, the R_0 value has varied between 1.1 and 2.6.

In 1851, the government of the French Republic organized the first of 14 international sanitary conferences to standardize quarantine regulations and encourage data sharing as ways to control cholera and other infectious diseases. These conferences became a template for other international organizations, culminating in the WHO.

In 1854, John Snow (1813 to 1858) became the acknowledged father of analytic epidemiology by elucidating what we now call a common-source outbreak. Acting on a hunch, Snow mapped the relationship of cholera deaths in the Soho district of London to the locations of wells from which people pumped water to carry home. A majority of deaths fell within a polygon surrounding a pump at the intersection of Broad and Cambridge Streets (now Broadwick and Lexington Streets). Authorities removed the pump handle, whereupon mortality declined. Snow died before general acceptance of his thesis, confirmed in 1884 when the German bacteriologist Robert Koch (1843 to 1910) isolated *Vibrio cholerae*.

The seventh cholera pandemic began in 1961 and is ongoing at the time of this writing. Its cause is the O1 El Tor biotype of the cholera bacillus. In 2019, there were nearly a million cases, with about 2,000 deaths, in 31 nations. Foci of cholera correlate with poor sanitation and living conditions. Global warming will make cholera increasingly problematic.

Influenza

From influenza, we learned how rapidly respiratory viruses can circumnavigate the globe, how global surveillance of a frequently mutating virus aids vaccine formulation, and how immunizing schoolchildren protects older persons. Other lessons include those learned from breakdowns in international collaboration, misinformation from news media, and resistance to "routine" immunization.

本书版权归John Wiley & Sons Inc.所有

The influenza A virus causes the annual "seasonal flu," punctuated several times each century by pandemic influenza after the virus undergoes a major change. The virus mutates continuously in the numerous wild and domestic birds that constitute its principal reservoir. Let us briefly review the shorthand for flu strains.

Neutralizing antibodies target surface glycoproteins on the influenza A virus known as the hemagglutinin antigen (HA, or H) and the neuraminidase antigen (NA, or N). These form the basis for shorthand designations of virus strains. To illustrate, "A/Hawaii/70/2019 (H1N1)" designates an influenza A virus first isolated in Hawaii, which was the 70th strain isolated during 2019 and which carries the type 1 hemagglutinin antigen and the type 1 neuraminidase antigen—hence, the virus subtype is H1N1.

The term "antigenic drift" refers to minor reassortments in the virus genome. "Antigenic shift" refers to major reassortments that produce a new virus subtype. Antigenic shifts were responsible for the 1918 "Spanish flu" pandemic (caused by an H1N1 subtype, resulting in an estimated 50 million deaths), the 1957 "Asian flu" (caused by an H2N2 subtype, resulting in about 1.5 million deaths), the 1968 "Hong Kong flu" (caused by an H3N2 subtype, resulting in about 1 million deaths), and the 2009 pandemic (caused by an H1N1 subtype, resulting in about 300,000 deaths).

Molecular monitoring of influenza A virus isolates enables experts to recommend strains to include in the vaccine for the next flu season. This virus continues to mutate during the 6 months required to make enough vaccine for distribution, and vaccine efficacy therefore varies from year to year. Data for the 10-year period from 2010–2011 to 2019–2020 indicate an average vaccine efficacy of 42% (range, 19 to 60%).

Children are at highest risk of influenza, but their symptoms are usually mild and nonspecific. Most flu-related deaths occur in older people and those with serious underlying conditions. Annual flu shots reduce not only influenza-related mortality but also all-cause mortality in older people.

A Japanese experience attests to the value of immunizing children to establish herd immunity and thereby reduce deaths among older adults. Flu shots were mandatory for Japanese schoolchildren between 1962 and 1987. Flu-related mortality in older adults declined during those years, only to return to baseline after governments lifted the mandates.

Public responses to the infamous Spanish flu pandemic of 1918–1919 included measures familiar more than a century later as the world copes with the COVID-19 pandemic: closure of institutions such as public schools, churches, and theaters; social distancing; use of masks; and cancellation of public events that would include large crowds. These efforts were uncoordinated in part because of World War I. U.S. President Woodrow Wilson barely acknowledged the pandemic but was not alone in this regard. Leaders of the warring nations disregarded the data-sharing agreements forged during the international sanitary conferences. The disease did not originate in Spain; it came to be called the Spanish flu only because Spanish authorities released their data, since their country was neutral during the war. Fake news proliferated. One conspiracy theory charged that German submarines had spewed the causative agent into Allied countries.

Red Cross chapters made masks and issued instructions on their use. Some western states in the United States passed mask ordinances. San Francisco became the first city to mandate masks, with fines for noncompliance. Citizens formed an Anti-Mask League. The "mask-slackers" prevailed. San Francisco as a result became one of the hardest-hit cities in the United States. Philadelphia became another disaster area after authorities allowed a Liberty Loans Parade to proceed despite knowing that influenza was heading their way from Boston and New York.

New avian influenza A virus strains continue to appear, raising the possibility that one or more of these—such as A/H5N1, A/H5N2, A/H7N3, or A/H7N9—could mutate in such a way as to spread easily from human to human. This possibility lends urgency to the search for a universal influenza vaccine.

HIV/AIDS

From HIV/AIDS came the realization that a novel, almost uniformly fatal disease could emerge seemingly out of nowhere and baffle the world's top scientists. Other lessons include those regarding new forms of social disruption and the power of the Internet to advance conspiracy theories.

HIV-1, the causative agent, arose from simian retroviruses. The pandemic possibly began with a single transmission from a chimpanzee to a human in southeastern Cameroon. On 5 May 1981, the CDC reported five cases of *Pneumocystis* pneumonia among men in Los Angeles who had sex with men. Epidemiologists quickly identified other risk groups: injection drug users, recipients of blood and blood products, newborn infants born to mothers with the disease, and healthcare workers. Between 1989 and 2013, the CDC received 58 confirmed and 150 possible cases of occupationally acquired HIV infection among healthcare workers in the United States. HIV/AIDS was almost uniformly fatal until 1995–1996, when effective drug combinations made it highly treatable.

The history of HIV/AIDS between 1981 and 1996 reads like a truncated history of medicine. In 1981, physicians knew little more about what was killing their patients than did the "plague doctors" of previous centuries. In 1983, French researchers isolated the responsible virus. In 1987,

本书版权归John Wiley & Sons Inc.所有

the U.S. Food and Drug Administration (FDA) approved zidovudine (AZT; now called ZDV) for therapy after researchers stopped a blinded trial at 24 weeks because those who received the drug lived longer than those who got the placebo. The promise of AZT proved illusory, because mutations in the RNA viral genome rendered the drug ineffective. Patients kept on dying. During 1995 and 1996, the FDA approved a new class of drugs, the protease inhibitors, enabling highly effective therapy with combinations of two or more drugs. The disease became "medicalized"; patients could now live near-normal lives. By 1996, it was possible to diagnose the illness, stage its severity, and determine the most effective drugs using a single blood sample.

The years between 1981 and 1996 were turbulent. Social protests included heckling of speakers at scientific meetings. Misinformation mushroomed, as did unproven therapies and conspiracy theories.

In retrospect, science afforded humanity a narrow escape. HIV-1 was the first known human pathogen combining a long incubation period with near-uniform mortality. It was possible to isolate the causative virus within 2 years only because researchers had discovered the enzyme reverse transcriptase in 1969—just 12 years before the five cases in Los Angeles. It was not until 1979, just 2 years before those cases, that the first human retrovirus, HTLV-1, was isolated. The HIV/AIDS pandemic could have been a lot worse.

Government responses in the United States included contact tracing, a massive education campaign, and federal legislation to assist uninsured and underinsured persons. HIV/AIDS remains a global problem, especially in sub-Saharan Africa, where recent data suggest an average R_0 value of 4.6.

Coronaviruses and COVID-19

Coronaviruses

At the time of this writing, about 200 coronaviruses have been isolated from bats, the primary reservoir. In 1965, researchers discovered the first of four coronaviruses now known to cause the common cold. Two of these are alphacoronaviruses that mainly cause upper respiratory symptoms ("head colds"), and two are betacoronaviruses that also cause lower respiratory symptoms ("chest colds"). The three coronaviruses of recent concern—the viruses that cause SARS (isolated in 2002), MERS (2012), and COVID-19 (2019)—are betacoronaviruses that attach to cells of the lower respiratory tract with significant morbidity and mortality.

Severe Acute Respiratory Syndrome

SARS is caused by SARS coronavirus 1 (SARS-CoV-1), which arose in the "wet markets" of the Guangdong province of China. Chinese scientists traced the virus to cave-dwelling horseshoe bats, from which it spread to palm civets and then to humans. The Chinese government responded slowly but later apologized. Significant outbreaks occurred in Hong Kong and Toronto. Rigorous control measures eradicated the virus within 7 months after 8,422 reported cases, of which 1,725 (12%) were in healthcare workers. The case-fatality rate was 11%, and some survivors had long-term sequelae.

The R_0 value of the SARS virus was perhaps 2.9 at the onset. Case identification and contact tracing, facilitated by the disease's long incubation period, reduced the R_0 value to an average of 0.49, whereupon the outbreaks subsided. Results of a meta-analysis suggest that N95 masks were about 80% effective at preventing transmission to healthcare workers. Among the healthcare workers who died was Carlo Urbani (1956 to 2003), an Italian physician-epidemiologist who identified the new disease in a Chinese-American businessperson and notified WHO authorities, who then took effective action.

Middle East Respiratory Syndrome

The first known case of MERS (caused by MERS-CoV) occurred in June 2012 in a 60-year-old Saudi Arabian man with pneumonia and renal failure. His physician sent a sample to a virologist in the Netherlands, who sequenced the virus and determined the cause of an outbreak within weeks. At the time of this writing, there have been more than 2,500 cases, mainly in Saudi Arabia, with a case-fatality rate of about 35%. The lesser bamboo bat is perhaps the main reservoir. The dromedary camel is clearly the intermediate host, and its centrality to Saudi Arabian life precludes eradication. The secondary attack rate runs high among healthcare workers; about 19% of cases are healthcare related; and in one study, the mortality among healthcare workers was 16%. The R_0 value was 8 during a 2015 outbreak in South Korea.

COVID-19 as a Four-Act Play

Let us now compare lessons from COVID-19 with those of previous epidemics and pandemics (Tables 50.1 and 50.2) and revisit Rosenberg's dramaturgic model.

Act One: progressive revelation. On 30 December 2019, a 34-year-old Chinese ophthalmologist named Li Wenliang (1985–2020) warned colleagues about a few mysterious cases of pneumonia. Officials interrogated and reprimanded Li, who died of COVID-19 less than 2 months later. On 2 January 2020, the WHO representative in China requested information, and, 3 days later, the WHO rang the alarm for its member nations. On 21 January, Chinese officials announced human-to-human transmission. They placed 18 million people under strict lockdown. On

本书版权归John Wiley & Sons Inc.所有

Table 50.1 Some lessons in science and public health learned from epidemics and pandemics prior to the 21st century and from COVID-19

Prior to the 21st century	In the first 2 years of the COVID-19 pandemic
Soap and other measures of basic hygiene (ancient civilizations)	Sales of soap and liquid hand hygiene products soared worldwide, with North America accounting for about 35% of the world market.
Social distancing (Hebrew Bible; plague; yellow fever; influenza)	German researchers determined that social distancing prevented 84% of predicted COVID-19 cases and 66% of deaths.
Face masks (plague; influenza)	Users of a smartphone application ("app") in the U.S. who self-reported that they "always" used a face mask during potential exposures experienced a 62% reduction of predicted COVID-19 cases even when living in communities that precluded adequate social distancing.
Importance of zoonoses (ancient civilizations, including proscription of bats as food in the Hebrew Bible; plague; yellow fever; influenza; HIV/AIDS)	Studies to the time of this writing suggest (i) bats were the ultimate origin of COVID-19; (ii) the virus possibly spread from bats to humans; and (iii) the virus possibly spread from bats to humans by way of an undetermined intermediate host.
Immunization (vaccines) to prevent infection (smallpox, yellow fever, influenza)	Manufacturers developed effective vaccines against COVID-19 in less than a year. Initial studies suggest, on average, about 90% efficacy for preventing infection and more than 95% efficacy for preventing death.
International collaboration between and among agencies concerned with disease prevention and control (cholera, HIV/AIDS)	The WHO responded effectively and efficiently to COVID-19. Data sharing among nations has been, for the most part, robust.
Immunization of schoolchildren to prevent mortality in older persons (influenza)	The benefits of immunizing children against COVID-19 to protect older adults remain hypothetical at the time of this writing.
Role of international travel in the causation of a pandemic (plague, smallpox, yellow fever, smallpox, influenza, HIV/AIDS)	Originating in China in December 2019, the virus spread to Italy by January 2020; initial cases in the U.S. came mainly from Europe; the virus soon became worldwide.
Closing institutions (schools, workplaces, businesses) and venues (influenza)	Results of a meta-analysis suggested school closing to be the most effective of these measures, but all of them work.
Contact tracing (HIV/AIDS)	Contact tracing was highly effective in China, Taiwan, and elsewhere. In the U.S., it helped to contain some outbreaks.
Quarantine (plague, yellow fever)	A review of 22 studies suggested quarantine of exposed persons could prevent 44 to 81% of new cases and 31 to 63% of deaths.
Use of descriptive and analytic epidemiology (plague, cholera)	The extent and sophistication of epidemiologic investigation probably exceed that of any pandemic in history.
Identification of the cause of a pandemic disease (plague, smallpox, yellow fever, cholera, influenza, HIV/AIDS)	Chinese scientists isolated the virus responsible for COVID-19 within weeks of the first reported cases, sequenced its genome, and shared the results with the global scientific community.
Global surveillance of viral isolates to detect mutations that may be of clinical importance (influenza)	The extent of surveillance and genome sequencing of SARS-CoV-2 isolates exceeded that of any previous disease, including influenza.
Drug therapy (influenza A—oseltamivir [Tamiflu] and zanamivir [Relenza] for treatment and prophylaxis, approved by FDA in 1999)	The FDA approved remdesivir (Veklury) for treatment in 2020.

31 January, the WHO declared a global public health emergency. On 20 February, Chinese scientists reported isolation of the causative agent, SARS-CoV-2, including the sequence of its genome, in the *New England Journal of Medicine*.

Act Two: management of randomness. It quickly became apparent that mortality was higher among the elderly and among persons with underlying conditions, including obesity. Concerning in the United States were the correlations of COVID-19 and death with poverty and

本书版权归John Wiley & Sons Inc.所有

Table 50.2 Some lessons in human behavior learned from epidemics and pandemics prior to the 21st century and from COVID-19

Prior to the 21st century	In the first 2 years of the COVID-19 pandemic
Denial of initial cases and/or downplaying the initial outbreak by officials (yellow fever, influenza, HIV/AIDS), including two U.S. presidents (influenza, HIV/AIDS)	Chinese officials silenced Li Wenliang, the ophthalmologist who privately warned colleagues about the new disease. Some U.S. officials, including the U.S. president, downplayed the pandemic.
Increased incidence and death rates among disadvantaged persons (plague, yellow fever, cholera)	Numerous reports documented a higher incidence and death rate in the U.S. among nonwhite populations. Variables associated with death also include advanced age, comorbidities, and poverty.
Conspiracy theories (Plague of Athens, cholera, influenza, HIV/AIDS)	Early conspiracy theories suggested COVID-19 was (i) an act of bioterrorism perpetrated by a Chinese laboratory or (ii) an attempt to discredit an incumbent U.S. president seeking reelection.
Misinformation and disinformation (influenza)	The U.S. press reported widespread misinformation and disinformation, spread by digital media and, notably, social media. The WHO used the term "infodemic."
Breakdown in international collaboration between and among health departments (influenza)	On 29 May 2020, the U.S. president informed the United Nations that the U.S. would withdraw from the WHO. He also called SARS-CoV-2 the "China virus."
Resistance to face masks (influenza)	Despite data showing the efficacy of face masks, resistance became widespread in the U.S.. Many felt mask mandates violated their freedom of choice, a phenomenon psychologists call "reactance."
Resistance to immunization (smallpox, influenza)	Despite data showing the efficacy of COVID-19 vaccines to prevent disease, and more especially to prevent hospitalization and death, resistance became widespread in the U.S. and notably among younger adults, whites, and persons with conservative worldviews.
Resistance to government mandates for control measures (influenza)	Authoritarian governments such as China enforced control measures, but the effectiveness of mandates in democratic nations has varied.
Bioterrorism (antiquity, Plague of Athens, smallpox)	Bioterrorism using coronaviruses has not been documented, despite rumors that SARS-CoV-2 originated in a laboratory.
Mistrust of science (plague, cholera, yellow fever, influenza, HIV/AIDS)	Psychologists determined that mistrust of science and beliefs in conspiracy theories correlated with low education, religious beliefs, and a predisposition to paranoia and suspicion.
Polarization of public opinion (plague, yellow fever)	Numerous studies indicated that, in the U.S., resistance to measures advocated by health authorities correlated with political-party affiliation.
Treatment recommendations based on scanty or insufficient data (yellow fever, HIV/AIDS)	Recommendations for antiparasitic drugs (hydroxychloroquine, ivermectin) drew enthusiasm despite the absence of well-controlled clinical trials.
Death threats to public officials (plague—death threats against Joseph J. Kinyoun, in whose laboratory the NIH originated)	Death threats were made against Anthony S. Fauci, director of the NIH National Institute of Allergy and Infectious Diseases and chief medical advisor to the U.S. president.
Xenophobia (Plague of Athens, plague, HIV/AIDS)	Racism and xenophobia were often reported, the most common bias being against persons of Asian descent, including Asian-Americans.
Undermining of democracy (Plague of Athens)	At least 78 countries or territories postponed or cancelled elections. Journalists determined that democratic values declined in 80 of 192 countries surveyed.

nonwhite ethnicity. Also concerning was the high risk of healthcare workers. By November 2021, the WHO reported about 115,000 deaths in healthcare workers worldwide. Nurses were especially vulnerable to anxiety and stress reactions.

Data on the basic reproduction number (R_0) varied considerably. The highest R_0 value (14.8) came from the confined quarters of a Japanese cruise ship. Analysis of 29 studies suggested a mean R_0 value of about 3 (2.9, with a 95% confidence interval of 2.4 to 3.4). In December 2020, the Delta variant of the SARS-CoV-2 was isolated in India and was shown to have an R_0 value of about 5 (mean, 5.08, with a range of 3.2 to 8 in various studies), indicating greater transmissibility. In November 2021, the Omicron variant was isolated in South Africa and was found in some studies to have an R_0 value of 7 or higher, indicating even greater transmissibility. The virus thus treats the play script as a work in progress, adding flashbacks to earlier scenes as each new mutant makes its entrance on the stage.

Act Three: negotiation of a public response. The U.S. FDA approved an antiviral drug within 10 months of the first report, a monoclonal antibody for therapy within 11 months, and a vaccine for emergency use within

本书版权归John Wiley & Sons Inc.所有

12 months. Laboratories throughout the world scanned viral isolates for mutations. Other researchers published data on the efficacy of such nonpharmaceutical measures as face masks, social distancing, quarantine, and contact tracing (Table 50.1). Clinicians got better at treating the disease.

Public responses varied from country to country. The Chinese government implemented effective lockdowns, face mask mandates, social distancing, and contact tracing. The democratic governments of Taiwan and New Zealand were equally effective. Baffling and concerning was the observation that the United States, with less than 5% of the world's population, had at one time 25% of the world's COVID-19 cases. Resistance to control measures in the United States sometimes correlated with political-party affiliation and gubernatorial preferences (5). Commentators suggested that COVID-19 would undermine democratic values, accelerating a global trend toward authoritarianism (6). The term "infodemic" entered the lexicon as a portmanteau of "information" and "epidemic," as social media spread misinformation and disinformation, undermining the expertise and recommendations of experts.

Act Four: subsidence and retrospection. We can only speculate whether the curtain will close completely or only partially on COVID-19. SARS-CoV-2 could easily become endemic, as have the four coronaviruses that cause the common cold. We can confidently predict that future historians (if such exist) will view COVID-19 as a foretaste of things to follow during the Anthropocene Epoch.

The Anthropocene and Future Epidemics and Pandemics

The Anthropocene Epoch

The Anthropocene Epoch holds the possibility of a "democracy of suffering" in which infectious diseases will be merely one of humankind's many problems (7). Further encroachment on the animate environment will give rise to zoonoses; global warming will drive the insect vectors of tropical diseases into temperate zones; and increasing population densities will facilitate disease transmission.

Threats Posed by Currently Known Infectious Agents

Most experts consider influenza A viruses to be the most likely cause of pandemics in the near future. A novel subtype of the influenza A virus, researchers predict, would claim at least 30 million lives.

Viral hemorrhagic fevers such as Ebola, hantavirus disease, Lassa fever, Marburg hemorrhagic fever, severe dengue, and yellow fever would probably cause smaller epidemics, if only because high case fatality rates would prompt lockdowns and vigorous contact tracing.

Mention should be made of a diverse group of 20 infections defined by the WHO as neglected tropical diseases (NTDs). These are "neglected" in the sense that they receive less attention and funding than such diseases as HIV/AIDS, tuberculosis, and malaria. The pathogens include viruses, bacteria, parasites (helminths and protozoa) (8), and fungi. NTDs currently affect about 1 billion people, about one-half of whom live in sub-Saharan Africa. Such social and environmental determinants as poverty, poor sanitation, limited access to clean water, mass migrations (including global urbanization and refugee crises), deforestation, dams, and climate change drive the emergence of NTDs in "developed" countries. These determinants explain, at least in part, the spread of dengue and chikungunya into new territories (9).

Potential Threats from Novel Pathogens

The Anthropocene could unmask an entirely new type of infectious agent, as was the case in 1981 with the retrovirus responsible for HIV/AIDS. Thawing of the polar caps could release viruses, bacteria, parasites, and other infectious agents that have been dormant for thousands or even millions of years. Malevolent individuals could use genetic engineering to create "designer" infectious agents with high transmissibility and high mortality, and for which we have neither diagnostic nor therapeutic capability.

Roles of Laboratories

Laboratory personnel at all levels—from the workbenches of community hospitals to the world's premier scientific institutes—will remain indispensable to the recognition, management, and elimination of epidemic and pandemic diseases. In 2001, for example, an alert technologist drew attention to Gram-positive bacilli in a spinal fluid specimen, assisting the discovery of an outbreak of anthrax due to apparent bioterrorism. In a larger sense, it behooves laboratory personnel to advocate for vaccines and for humanized science, which, along with reason, constitutes humanity's best hope for long-term survival (10, 11).

The WHO maintains a list of viral pathogens with the ability to cause global pandemics and epidemics. The WHO and the NIH assign infectious agents or toxins to risk groups depending on the likelihood of their causing serious disease in humans. Agents in risk group 1 pose little or no risk to the individual or to the community, while risk group 2 agents present moderate risk to individuals but low risk to the community. Risk group 3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available; they represent a high risk to individuals but low risk to the community. Risk group 4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. They pose high

本书版权归John Wiley & Sons Inc.所有

Table 50.3 Priority viral pathogens deemed by the WHO to have the ability to cause global pandemics and epidemics, and associated risk groups[a]

Pathogen or disease	Disease description	Mortality rate/R_0 value[b]	Risk group
Chikungunya virus (*Alphavirus*)	Acute viral illness with joint pain/swelling	~12%/0.46–6.46 (mean, 2.55)	3
Congo-Crimean hemorrhagic fever	Viral hemorrhagic fever	Unknown	4
Dengue virus (*Alphavirus*)	Acute viral illness with rash, joint pain/swelling, and hemorrhagic fever in severe cases	2–25%/0.67–65 (mean, 4.74)	2
Filoviruses (Ebola and Marburg)	Viral hemorrhagic fever	24–90%/1.51–2.53	4
Influenza virus	Influenza-like illness	<1%/0.9–2.1	2
Lassa fever	Viral hemorrhagic fever	1–15%/~1.3	3
MERS-CoV	Influenza-like illness	~35%/~1	3
Monkeypox (*Orthopoxvirus*)	Smallpox-like illness	10%/0.32–2.13	4
Nipah and henipaviral diseases	Severe viral infection with initial influenza-like symptoms and encephalitis	40–75%/0.48	4
Novel coronavirus	Influenza-like illness	Unknown	Initially unknown
Rift Valley virus (*Phlebovirus*)	Rift valley fever is an acute viral illness that may progress in severe cases to hemorrhagic fever and encephalitis.	<1%/23–25	Currently unclassified
Betacoronavirus (SARS-CoV)	Influenza-like illness	~10%/<1–2.75	3
Betacoronavirus (SARS-CoV-2)	Influenza-like illness	1–2.5%/1.5–3.5	2 (routine viral diagnostic tests) or 3 (viral culture)
Variola virus (*Orthopoxvirus*)	Smallpox	30%/5–7	4
Flavivirus	Yellow fever	20–50%/1.35–11 (median, 4.81)	3
Zika virus	Acute viral illness with rash	Not fatal/0.16–9.4 (mean, 3.02); birth defects and linked to Guillain-Barré syndrome	2
Virus X	Unknown		

[a] For definitions and abbreviations, see the text and glossary.
[b] "Unknown" indicates that R_0 has not been defined.

risk to both individuals and the community. These risk groups do not always correlate with the hazard posed to laboratory personnel (Table 50.3).

SUMMARY

Lessons from previous centuries add perspective to what we learned during the first 2 years of the COVID-19 pandemic. These lessons provide background for appreciating the One Health concept (see chapter 51), planning for future pandemics (see chapter 52), and exploring newer laboratory technologies as they may apply to emerging infectious diseases (see chapter 53).

KEY POINTS

- Epidemics and pandemics are unintended consequences of civilization.
- Lessons from COVID-19 echo those of previous epidemics and pandemics.
- COVID-19 will probably prove to have been a mild foretaste of things to come in the Anthropocene Epoch, in which we now live.
- Laboratory personnel should advocate for humanized science and reason as the best hope for long-term survival of *Homo sapiens*.

GLOSSARY

Aerosol transmission Transmission of an infectious agent caused by dissemination of small particles (droplet nuclei ≤5 μm in diameter) that remain infectious when suspended in air over long distances and time. *See also* Droplet transmission.

AIDS Acquired immunodeficiency syndrome; caused by HIV-1.

Analytic epidemiology The aspect of epidemiology concerned with identifying health-related causes and effects.

Anthropocene Epoch The proposed geologic epoch in which human activity has become the dominant cause of climate and

本书版权归John Wiley & Sons Inc.所有

environmental change. There is disagreement whether to date its onset to (i) the beginning of agriculture and domestication of animals, about 10,000 to 12,000 years ago; (ii) the onset of the industrial revolution during the late 1700s; or (iii) the detonation of the atomic bomb in 1945.

Antigen Any substance that causes the body to make an immune response (such as the formation of antibodies) against that substance.

Applied epidemiology The application or practice of epidemiology to address public health issues.

Attack rate A variant of the incidence rate, applied to a narrowly defined population observed for a limited period, such as during an epidemic.

Basic reproduction number *See* R_0.

Biovar A variant prokaryotic strain that differs physiologically or biochemically from other strains of a particular species.

Biotype A group of organisms having an identical genetic constitution.

Carrier A person or animal without apparent disease who harbors a specific infectious agent and is capable of transmitting the agent to others.

Case fatality rate The proportion of persons with a particular condition (cases) who die from that condition. The denominator is the number of incident cases; the numerator is the number of cause-specific deaths among those cases (see also Mortality rate).

COVID-19 Coronavirus disease 2019, a respiratory and systemic disease caused by SARS-CoV-2.

CDC Centers for Disease Control and Prevention (U.S.), headquartered in Atlanta, GA.

Cluster An aggregation of cases of a disease or other health-related condition, closely grouped in time and place. The number of cases may or may not exceed the expected number; frequently the expected number is not known.

Common-source outbreak An outbreak that results from a group of persons being exposed to a common noxious influence, such as an infectious agent or toxin.

Contact tracing The process of attempting to identify persons who have been in recent contact with someone diagnosed with an infectious disease, in order to notify them of the exposure, to recommend quarantine, and/or to offer treatment.

Descriptive epidemiology The aspect of epidemiology concerned with organizing and summarizing health-related data according to time, place, and person.

Direct transmission The immediate transfer of an agent from a reservoir to a susceptible host by direct contact or droplet spread.

Disinformation False information deliberately created and disseminated with malicious intent. *See also* Misinformation.

Droplet nuclei The residue of dried droplets that may remain suspended in the air for long periods, may be blown over great distances, and are easily inhaled into the lungs and exhaled. *See also* Aerosol transmission.

Droplet transmission (spread) The direct transmission of an infectious agent from a reservoir to a susceptible host by spray with relatively large particles (5 to 10 μm in diameter) contained in the short-range aerosols produced by sneezing, coughing, or talking. *See also* Aerosol transmission.

Emerging infectious diseases Infectious diseases that have newly appeared in human populations, are rapidly increasing in incidence and/or geographic range, or are caused by pathogens that are considered of high risk to public health and/or national security.

Endemic disease Disease (or infectious agent) constantly present within a given geographic area or population group; may also refer to the usual prevalence of a given disease within such an area or group.

Environmental factor An extrinsic factor (geology, climate, insects, sanitation, health services, etc.) which affects the agent and the opportunity for exposure.

Epidemic The occurrence of more cases of disease than would be expected in a given area or among a specific group of people over a particular period.

Epidemic curve A histogram that shows the course of a disease outbreak or epidemic by plotting the number of cases by time of onset.

Epidemiological triad The three components of the classic model of infectious disease causation: an infectious agent, a susceptible host, and an environment that brings the host and agent together, resulting in disease.

FDA Food and Drug Administration (U.S.).

Genome All of the genetic information for an organism, consisting of the nucleotide sequences of DNA or, for an RNA virus, the nucleotide sequences of RNA.

Herd immunity *See* Immunity, herd.

High-risk group A group in the community with an elevated risk of disease.

HIV Human immunodeficiency virus.

HIV/AIDS Human immunodeficiency virus infection and acquired immunodeficiency syndrome (a hybrid term denoting the spectrum of conditions caused by infection with HIV).

Host A person or other living organism that can be infected by an infectious agent under natural conditions.

Hyperendemic disease A disease that is constantly present at a high incidence and/or prevalence rate.

Immunity, active Resistance developed in response to stimulus by an antigen (infecting agent or vaccine) and usually characterized by the presence of antibody produced by the host.

Immunity, herd The resistance of a group to invasion and spread of an infectious agent, based on the resistance to infection of a high proportion of individual members of the group.

本书版权归John Wiley & Sons Inc.所有

The resistance is a product of the number of susceptible individuals and the probability that these individuals will be exposed to an infected person.

Immunity, passive Immunity conferred by an antibody produced in another host and acquired naturally by an infant from its mother, or artificially by administration of an antibody-containing preparation (antiserum or immune globulin, including a monoclonal immune globulin).

Incidence rate A measure of the frequency with which an event, such as a new case of illness, occurs in a population over a period. The denominator is the population at risk; the numerator is the number of new cases occurring during a given time period.

Incubation period The time between exposure to an infectious disease and the onset of clinical symptoms and/or signs of disease. *See also* Latency period.

Indirect transmission The transmission of an agent carried from a reservoir to a susceptible host by suspended air particles or by animate (vector) or inanimate (vehicle) intermediaries.

Infectivity The proportion of persons who after being exposed to a causative agent become infected (that is, the agent multiplies in the body).

Infodemic Excessive information ("info-") about an epidemic ("-demic") spread especially by digital media and including false and misleading information.

Latency period The time between exposure to an infectious disease and the onset of infectiousness (the ability to transmit the disease to others). *See also* Incubation period.

MERS Middle East respiratory syndrome, a viral respiratory infection caused by MERS-CoV, identified in 2012 in Saudi Arabia.

MERS-CoV Middle East respiratory syndrome coronavirus

Miasma theory The obsolete idea that diseases such as plague, cholera, and malaria were transmitted by miasmas ("bad air" or "night air") arising from decaying organic matter.

Misinformation False information shared by people who do not intend to mislead others. *See also* Disinformation.

Morbidity Any departure, subjective or objective, from a state of physiological or psychological well-being.

Mortality rate A measure of the frequency of occurrence of death in a defined population during a specified interval of time (*see also* Case-fatality rate).

N of a disease The temporal course of a disease from onset (inception) to resolution.

Neglected tropical diseases (NTDs) A diverse group of 20 conditions identified by the World Health Organization that are prevalent mainly in tropical areas, mostly affect impoverished communities, and disproportionately affect women and children.

Neutralizing antibody An antibody that binds to a virus particle, interfering with its ability to infect a host cell.

NIH National Institutes of Health (U.S.).

Nosocomial Acquired or occurring in a hospital, as opposed to the community; healthcare related.

Outbreak Synonymous with epidemic; sometimes the preferred term, since "epidemic" is more likely to evoke sensationalism. Alternatively, a localized as opposed to generalized epidemic.

Pandemic An epidemic occurring over a very wide area (several countries or continents) and usually affecting a large proportion of the population. Criteria for a pandemic include (i) an illness often resulting in death, (ii) sustained person-to-person spread, and (iii) worldwide spread.

PCR Polymerase chain reaction.

Prevalence The number or proportion of cases or events or conditions in a given population.

Prevalence rate The proportion of persons in a population who have a particular disease or attribute at a specified point in time or over a specified duration of time.

Public-health surveillance The systematic collection, analysis, interpretation, and dissemination of health data on an ongoing basis, to gain knowledge of the pattern of disease occurrence and potential in a community, in order to control and prevent disease in the community.

Reassortment The mixing of genetic material of a species (including that of a virus) into new combinations.

Relative risk A comparison of the risk of a health-related event such as disease or death in two or more groups.

Reservoir The habitat in which an infectious agent normally exists and multiplies; reservoirs include human reservoirs, animal reservoirs, and environmental reservoirs.

Retrovirus A type of RNA virus that, after entering a host cell, uses the enzyme reverse transcriptase to make a DNA copy of its RNA genome.

Risk factor An aspect of personal behavior or lifestyle, an environmental exposure, or an inborn or inherited characteristic that is associated with an increased occurrence of disease or other health-related event or condition.

R_0 ("R naught") A mathematical figure expressing the average number of cases of an infectious disease that arise from a single infected individual, in a population that has not previously experienced the disease. Also known as "basic reproduction number."

SARS Severe acute respiratory syndrome, caused by SARS-CoV-1, identified in 2002.

SARS-CoV-1 (also known as SARS-CoV) Severe acute respiratory syndrome coronavirus, the cause of SARS.

SARS-CoV-2 Severe acute respiratory syndrome coronavirus 2, the cause of COVID-19.

Seasonality Change in physiological status or in disease occurrence that conforms to a regular seasonal pattern.

Secondary attack rate A measure of the frequency of new cases of a disease among the contacts of known cases.

本书版权归John Wiley & Sons Inc.所有

Surveillance *See* Public-health surveillance.

Syndrome A cluster of symptoms and signs of illness that consistently occur together, thus appearing to constitute a disease even if the cause has not been identified.

Transmission of infection Any mode or mechanism by which an infectious agent is spread through the environment or to another person.

Universal precautions Recommendations issued by Centers for Disease Control and Prevention (CDC) to minimize the risk of transmission of blood-borne pathogens, particularly HIV and hepatitis B virus, by healthcare and public safety workers. Barrier precautions are used to prevent exposure to blood and certain body fluids of all patients.

Variable Any characteristic or attribute that can be measured.

Variant of a virus An isolate of a previously known virus whose genetic material (genome) differs from the reference virus because of one or more mutations in its DNA or RNA.

Vector An animate intermediary in the indirect transmission of an agent that carries the agent from a reservoir to a susceptible host.

Vehicle An inanimate intermediary in the indirect transmission of an infectious agent that carries the agent from a reservoir to a susceptible host.

Virulence The proportion of persons who after becoming infected by a causative agent develop clinical illness.

WHO World Health Organization.

Zoonosis An infectious disease that is transmissible under normal conditions from animals to humans.

REFERENCES

1. **Wu Q, Li Q, Lu J**. 2022. A One Health strategy for emerging infectious diseases based on the COVID-19 outbreak. *J Biosaf Biosecur* **4**:5–11.

2. **Carrasco-Hernandez R, Jácome R, López Vidal Y, Ponce de León S**. 2017. Are RNA viruses candidate agents for the next global pandemic? A review. *ILAR J* **58**:343–358.

3. **Lucey DR, Sholts S, Donaldson H, White J, Mitchell SR**. 2017. One Health education for future physicians in the pan-epidemic "Age of Humans." *Int J Infect Dis* **64**:1–3.

4. **Rosenberg C.** 1992. *Explaining Epidemics and Other Studies in the History of Medicine*, p 278–292. Cambridge University Press, New York, NY.

5. **Kincaid J, Leckrone JW**. 2020. Partisan fractures in U.S. federalism's COVID-19 policy response. *State Local Gov Rev* **52**:298–308.

6. **Repucci S, Slipowitz A**. 2020. *Democracy under Lockdown: The Impact of COVID-19 on the Global Struggle for Freedom*. Freedom House, Washington, DC. https://freedomhouse.org/sites/default/files/2020-10/COVID-19_Special_Report_Final_.pdf.

7. **Dufresne T.** 2019. *The Democracy of Suffering: Life on the Edge of Catastrophe, Philosophy in the Anthropocene*. McGill-Queens University Press, Montreal, Quebec, Kingston, Ontario, Canada.

8. **Hotez PJ**. 2016. Southern Europe's coming plagues: vector-borne tropical diseases. *PLoS Negl Trop Dis* **10**:e0004243.

9. **Hillyer JF**. 2020. Parasites and parasitology in this SARS-CoV-2, COVID-19 world: an American Society of Parasitologists presidential address. *J Parasitol* **106**:859–868.

10. **Hotez PJ**. 2021. *Preventing the Next Pandemic: Vaccine Diplomacy in a Time of Anti-Science*. Johns Hopkins University Press, Baltimore, MD.

11. **Pinker S.** 2018. *Enlightenment Now: The Case for Reason, Science, Humanism, and Progress*. Viking, New York, NY.

本书版权归John Wiley & Sons Inc.所有

51

Introduction
Pandemics in the Anthropocene: the Call for Transformative Change
What Is One Health?
One Health Thinking for Pandemic Risk Management
One Health Intelligence
Operational Impediment and Opportunities
Confronting the Reality of Complexity
Being Multifaceted • Being Multisolving • Being Adaptive
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES

One Health in Pandemic Planning, Prevention, and Response

Craig Stephen

OBJECTIVES

To introduce the concept of One Health and how it relates to a transformative pandemic agenda

To explore how One Health thinking can help overcome factors that limit preparedness, readiness, and resilience to emerging threats

To introduce operational impediments and opportunities for using One Health thinking in pandemic risk management

To introduce some competencies for managing the complex dynamic nature of pandemic risk management

Things that never happened before happen all the time.
Scott D. Sagan, *The Limits of Safety* (1993; quoted in reference 1)

There is something comfortable about planning pandemic programs by seeing cause-effect relationships as stable, linear, and predictable. But health sciences have recognized that disease emergence is the product of a system of complex, dynamic social and ecological interactions and that surprises are normal in such systems (2). Despite promises of scientific and technological means to improve our ability to predict impending threats, there is not enough predictive power to accurately forecast health outcomes resulting from the environmental and social changes anticipated in the 21st century (3). Anthropogenic environmental changes are piling on top of existing natural variability, globalized economies, and rapid social change to create a situation wherein past conditions are less reliable indictors of future conditions. Pandemic managers and researchers must anticipate change but should not expect to be able to predict it (4).

The future of pandemics in the Anthropocene will be replete with "foreseeable unexpected events." They will be foreseeable in that our experiences and research will reveal the possibility of new emerging diseases. They will be unexpected because we can rarely predict their timing, location, and impacts with sufficient accuracy to inspire proactive responses that are launched before a harm is manifested. Unexpectedness will generally come from lack of sufficient knowledge, operational factors that limit our openness to surprise,

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch51.

本书版权归John Wiley & Sons Inc.所有

and the basic dynamics of complex adaptive systems (5). This chapter explores each of these elements of surprise for pandemic preparedness using a One Health lens.

Pandemics in the Anthropocene: the Call for Transformative Change

A transformative pandemic agenda needs more than just better disease control. It also must provide a mechanism for building a system of interdependent and mutually supportive actions to promote health and resilience today and in the future. Humanity is facing pandemics of our own design that are being mediated through our perturbed relationship with our environments and animals. To keep pace with the unprecedented rate of emerging disease threats, innovations in knowledge creation and knowledge dissemination are urgently needed to ensure sustainable and reciprocal health benefits at the interface of people, animals, and their shared environments. Without transformation to address root causes of pandemic preparedness and resilience, we will continue to battle new crises as they emerge. A transformative pandemic agenda challenges researchers, policy makers, and health providers to collaborate to better use what we already know by bringing in a broader scope of knowledge to promote innovative public health approaches. Removing disciplinary barriers is a prerequisite to such innovation (6).

Too often a real or perceived crisis is the signal to launch an emerging-disease management action. Systems are rarely in place to find preclinical early warning signals, identify circumstances conducive to a disease emergence, or detect an outbreak before significant impacts arise (7). Effective epidemic responses require an integrated cycle of actions deployed before, during, and after a disease emerges (8). There are four components to this action cycle: (i) preventing or mitigating the impact of a hazard; (ii) ensuring that a population, agency, or community is prepared to act if an impact or risk emerges; (iii) providing an effective response immediately after a hazard's impact is detected; and (iv) helping the affected populations, communities, and systems recover from the impacts.

Pandemics like avian influenzas, coronavirus disease 2019 (COVID-19), and antimicrobial resistance, along with climate change, have shown that the grand health challenges of the Anthropocene are made up of multiple, simultaneous assets, deficits, and problems that interact to pull us closer to or further from critical tipping points. Responses that react to these grand challenges after harms occur and in disciplinary silos have been unable to get ahead of the unprecedented social and environmental changes of the 21st century. Unconnected approaches to comanaging the health of people, animals, and environments are failing to meet today's complex health challenges and are proving to be unsustainable (9). In a world of concurrent health and environmental problems, unique solutions for each problem are neither feasible nor effective (10). One Health is being called upon to open innovative and transformational avenues to prepare humanity to confront and cope with global health security threats tied to human development and environmental crises including pandemic infections.

What Is One Health?

At the heart of One Health is the desire for all species and generations to reach their full health potential. One Health promotes multiple sectors to work together to design and implement programs, policies, legislation, and research to achieve optimal health outcomes recognizing the interconnection between people, animals, and their shared environment. One Health was initially conceived by the Wildlife Conservation Society as an integrated, holistic, and preventative approach to diseases at the human-animal-environment interface. What started as a plan to reduce overexploitation of wildlife became a framework for collaboration to combat emerging infectious diseases. The One Health emphasis on multi- and interdisciplinary approaches extended veterinary public health from its focus on biomedical interventions targeting single hazards to a team approach that examines multiple dimensions of a shared problem. This in turn opened lines of investigation and action derived from the socio-ecological model of health.

The core ethos of One Health thinking is the value of multiple sectors working together and recognizing their interdependence. By working together, partners combine strengths to leverage knowledge, expertise, reach, and resources as they work toward better health outcomes for all. One Health approaches are adaptable to a wide range of local solutions to enhance emergency responses, reduce vulnerability to emerging threats, and increase resilience to complex and persistent challenges (11). Despite these generalities, there is no single, universally recognized definition of the term "One Health."

One Health relies on multiple disciplines with many underlying theories and practices. The relative weight of each subdiscipline varies from project to project depending on the problem, location, people, and funder. There are, however, three basic and complementary One Health "brands" (12). The first emphasizes the connection and exchange of emerging zoonotic pathogens and parasites. This brand focuses on building new capacity to find pathogens and parasites that could jump and flow between species. It seeks means to control emerging zoonotic disease threats to people by preventing or controlling them in the animal sources or reservoirs. The second brand adds attention to endemic zoonoses and animal diseases that affect human health outcomes and determinants of human health. Efforts include eliminating livestock diseases to produce more affordable and available food to combat food

本书版权归John Wiley & Sons Inc.所有

insecurity and malnutrition, reducing endemic zoonoses that keep people in poverty or ill, and sustaining wildlife populations to maintain ecological services and protect traditional uses of wildlife by indigenous populations. The third One Health brand emphasizes building resilience against megathreats like climate change, urbanization, and pandemics by concurrently protecting determinants of health for people, animals, and environments and, in doing so, protect capacities to cope with and bounce back from shocks. This brand emphasizes interspecies and intergenerational health equity. The bulk of investment and scholarship remains focused on the first brand. What binds the different One Health brands is a shared desire to protect and promote the health of people, animals, and environments more effectively and simultaneously through collaborative efforts of multiple disciplines working locally, nationally, and globally.

One Health Thinking for Pandemic Risk Management

There are many peer-reviewed and gray literature publications that examine portions of pathogen spillover cascades or actions/activities that are linked to the traffic of pathogens and parasites between people and animals. There is also a growing body of literature proposing means to impede this traffic. The intent of this chapter is neither to inventory that literature nor to propose targeted interventions. This is for two reasons. First, strong social influences on and the ecological context of the origins and spread of emerging pathogens create concerns about the generalizability of research on emerging-pathogen spillover cascades across social and ecological contexts. Second, there is a wide implementation and program evaluation gap in terms of how to prevent emerging infections by manipulating animal or ecosystem health. As population health interventions result in and occur as a series of interrelated and interacting events within a broader system, intervention effects are modulated by the context in which they are implemented. Care must, therefore, be taken in transferring evidence generated in one context to another (13). Instead, this chapter explores how One Health thinking can help overcome factors that limit our ability to access and interpret information that may affect preparedness, readiness, and resilience to emerging threats.

One Health Intelligence

The COVID-19 pandemic showed how the velocity of social and ecological change can lead to swift spread of emerging diseases and result in governments scrambling to keep pace with unanticipated threats. Governments cannot rely only on early signals of morbidity and mortality to make strategic decisions on the allocation of surveillance or management resources and expect to be ahead of disease outbreaks. The COVID-19 crisis revealed the need for proactive tools to generate intelligence for efficient resource deployment for precrisis threat management.

Animal signals for early warning. There is a long history of animals serving as sentinels for the effects and distribution of pathogens and pollutants (14, 15). Animal surveillance can provide signals that inspire individuals, communities, and/or organizations to respond in a timely and appropriate manner to avoid, reduce, or mitigate harm. Given animals' roles as sources of new and emerging infections, their position at the interface between the natural environment and people, and their intimate and ongoing interaction with their environment, animals can signal changing exposure risks important to public health. They do this by revealing the presence of pathogens circulating in an environment, elucidating the biological effects of new pathogens, and/or manifesting the introduction or emergence of a pathogen before it is discernible in people (16). Animal sentinels can document changes in host ranges, host responses to pathogens, and the relationships between hosts (17).

The attributes of the ideal sentinel species vary with the objective of the surveillance system, but in general, a good sentinel species (i) is sufficiently abundant or resistant to the impacts of sample collection that surveillance activities do not have significant impacts on the population, (ii) is easy to identify and find, (iii) is in the same exposure pathways as the populations of interest, and (iv) has measurable responses to the changes of interest; in addition, there should be a large body of information on the species' pathophysiology and ecology (18). There are, however, no standard, evidence-based guidelines for the use of animal sentinel data in general (17) or specifically for emerging diseases. This reflects (i) the challenge of deciding the threshold of animal signals that will elicit public health action in the absence of human diseases or infection, (ii) the influence of local macro- and microfactors affecting pathogen spillover or emergence risk, (iii) the dearth of assessments of animal sentinels for early warning surveillance, and (iv) insufficient time for surveillance systems to have been operating to determine the circumstances under which animal health changes precede human health impacts (16).

There are four significant limitations to animal signals for public health warning. First, detection and early warning systems and technologies tend to focus on a limited number of known signals (most often known etiologic agents or pathognomonic signs). A hazard-by-hazard approach to risk management is insufficient to ensure pandemic preparedness when the next hazard cannot reliably be predicted (2). Not only may this focus miss unanticipated pathogens and fail to provide contextual information

本书版权归John Wiley & Sons Inc.所有

on changing vulnerabilities, but also, the technologies and systems for early warning are not widely available in the most disadvantaged and vulnerable countries (19). Second, zoonotic disease in animals is often not legally mandated to the same extent as in humans, particularly in wildlife. This often means that emerging disease surveillance programs attempting to include animal and human data are challenging to design, interpret, and operate (20). Third, evaluations of emerging zoonosis surveillance systems are rarely found in the published literature, making it difficult for decision makers to produce evidence-based assessments of the design or interpretation of early warning systems (20, 21). Fourth, the usual animal disease surveillance goal is early detection of harms to quickly minimize their effects. This contrasts with the need to access and collect the relevant social and ecological information that shapes the vulnerability of a population or place to prioritize hot spots to efficiently deal with known threats and find cold spots for preemptive action to prevent the emergence of new hot spots (22).

There are generally five hierarchy steps that need to be spatially and temporally aligned to allow spillover of a zoonotic pathogen from animals to people: (i) a source (or reservoir) host of the pathogen must exist, (ii) that host must be infected, (iii) the pathogen must be released from the source host into an environment that allows its transmission to a spillover host and be able to survive in that environment to remain viable until the spillover host is exposed, (iv) the spillover host must be exposed to a sufficient quantity of viable pathogen to allow for an effective exposure, and (v) the spillover host must be susceptible to the pathogen (23). After this initial sequence, either there need to be ongoing exposures from the source host to maintain infections in spillover hosts or the pathogen must be able to be maintained in the spillover population without the need for the source host's contributions. In theory, interrupting one step in this cascade should prevent the spillover of a pathogen from a source animal population to other populations, assuming that only one spillover cascade is generating the risk. However, traditional zoonotic disease surveillance tends not to gather intelligence on all steps. Assumptions are often made about causal pathways based only on the detection of the pathogen in an animal host. Examination of the cascade of the five pathogen spillover preconditions needs information on both the pathogen and the socio-ecological settings to predict higher-risk areas (24). For example, understanding the process that brings source and spillover hosts together needs more than contact and spatial overlap mapping. It also needs ecological and anthropological studies identifying historical, social, and environmental processes affecting the contact network (25). A lack of data and attention to the dynamics of cross-species transmission has been noted in zoonotic disease models (26). Unfortunately, "systems where data have been collected at all levels in the spillover process are rare, or nonexistent, and require investment and sustained effort across disciplines" (27). Reporting biases can further complicate efforts to assess various steps in spillover using preexisting data (28).

Pandemic vulnerability intelligence. Although emerging diseases may be surprising, they do not arise by chance. Changes in how people interact with animals and the natural world affect the frequency and severity of emerging diseases (29). The drivers of pandemics lie in sociology and ecology. However, the large combination of species, spaces, and harms to consider when planning a pandemic program agenda is overwhelming, and resources to deal with them are limited. Vulnerability intelligence can be an initial step in identifying which species or human-animal interactions (i) are more prone to pathogen or parasite exchange between people and animals; (ii) involve animals more susceptible to amplifying emerging pathogens; and (iii) are particularly vulnerable, due to factors such as the effects of concurrent disease, or social or environmental constraints that reduce the capacity to resist or bounce back from a disease outbreak. Identifying vulnerable situations in advance of harms allows for strategic allocation of surveillance and management resources to enhance early threat detection, provide contextual information to forecast the implications of new hazard detection, and provide opportunities to reduce vulnerabilities to proactively decrease risk.

Landscape changes, climate change, invasive species, urbanization, globalization, and pollution all affect the occurrence of animal diseases and their impacts on socially valued outcomes (30–32). Pandemic warning needs a connected system of human intelligence distributed throughout the causal chain of a pandemic that can combine hazard surveillance with population reconnaissance that identifies socio-ecological system changes in vulnerability (2). One Health intelligence that provides collective and cooperative action to access and understand new knowledge from diverse sources would need to:

- Collect data on the nature and distribution of the social, health, and animal harms as opposed to tracking only the etiological causes of harms, such as pathogens, or tracking only adverse outcomes like diseases or deaths
- Recognize that pandemic pathogens are not likely to be eliminated in the short term and therefore seek information on variables that can pragmatically be manipulated to reduce animal and human vulnerability to harms
- Develop an information network that reveals feasible options to help populations cope with emerging diseases within the current circumstances while efforts to eliminate these diseases are ongoing

本书版权归John Wiley & Sons Inc.所有

- Recognize that actions attacking one harm may have unintended consequences for other harms, necessitating integrated analysis
- Actively engage a diversity of players and disciplines to find pathways and control points that can be targeted to reduce harms across various perspectives, priorities, and values

Pandemic intelligence, therefore, relies on information from multiple sources to provide a stream of information that can be inspected to support decisions about prevention, surveillance, or responses (33). Pandemic planners need to reconceive early warning surveillance as a system made up of a chain of subsystems, each with its own knowledge of an aspect of the social and ecological drivers of pandemics. This cannot be achieved by retaining focus solely on what is within a single domain of practice, yet there remain significant operational barriers to system-level, cross-sector intelligence.

Operational Impediment and Opportunities

Pandemic preparedness, prevention, and response benefit from scoping problems broadly to generate a richer understanding of complex system dynamics, a more accurate and comprehensive assessment of uncertainties, and deeper insights into potential health threats (34). Managing in the face of these complexities, uncertainties, and ambiguities requires effective, respected, and trusted collaborations to gather information and perspectives to better anticipate future vulnerabilities. Because no single sector has full control over the variety of factors that determine vulnerability to emerging diseases, effective solutions require multisectoral coordination, collaboration, and engagement.

The need for intersectoral collaborations cannot be overemphasized, but the challenges of incorporating One Health into pandemic planning should not be underestimated. Despite an urgency for interdisciplinary work, most pandemic programs remain bound to disciplinary conventions. Rarely is it anyone's job to "pull it all together" and form the professional connections required to cultivate the human intelligence needed to acquire and assess vulnerability signals coming from different sectors. Preemptive and strategic risk management is unlikely unless someone is assigned to integrate diverse warning signals and bring them back to a collaboration of organizations able to deploy their shared capacities and understandings towards shared goals. Program impact and sustainability will decline quickly when program activities fall victim to departmentalization and specialization (2). Public health is often a "prisoner of the proximate" in the sense that it prioritizes studies of relatively proximate causes of disease at the expense of a synthesis from a spectrum of fields to help see the breadth of the emerging challenge and be exposed to other ways of conceiving solutions (35). Although there is general agreement about the complex and codependent interplay among individual, environmental, ecological, and social factors influencing pandemic risk, there is typically a disconnection between the multiple policies, practices, and perspectives influencing pandemic risk (2). Agencies can misestimate pandemic threats when the links between policy, intelligence, warning, and response fail (36).

There are three preconditions for effective cross-sectoral pandemic readiness (adapted from reference 37). First, organizations need protocols, perspectives, communications, and cross-agency relationships that make them receptive to warning signals outside their usual scope of practice and apt to bring this information into decision making. Second, bureaucratic conflicts and overcrowded agendas must be managed to allow time and resources to cultivate collaborative actions on determinants of vulnerability that extend beyond immediate interests. This requires investment in developing partnerships to understand or influence socio-ecological causes of pandemic vulnerability. Third, personal attributes such as insensitivity to new information, perceived power dynamics, cognitive overload, and wishful thinking must be managed to avoid failure or unwillingness to recognize and act on very early warning signals.

Successful One Health collaborators see their role and responsibilities to help reduce pandemic risks and harms extending beyond their interests rather than seeing the issue as someone else's problem. For example, rather than blaming wildlife for public health risks (such as bats and COVID-19), One Health team members would work concurrently and collectively not only to reduce human exposure to bats but also to create environmental conditions unfavorable to disease transmission and persistence in bat populations. Pandemic programs must be attentive to the interspecies and intergeneration implications of interventions to prevent or reduce the unintended consequences of an emerging disease response. For example, culling fruit bats in Uganda to eliminate the virus source of human Marburg virus infections inadvertently increased virus prevalence in the bat colony due to the interplay of bat ecology and immunology (38). This example illustrates that an intervention focused solely on protection of human health (i.e., elimination of the bats) not only did not solve the problem but also caused harm to a wildlife population while simultaneously increasing the risk of spillover to humans. As another example, many nongovernmental and governmental organizations have proposed temporary or permanent closure of markets selling wildlife or wildlife products for food or medicines as a pandemic prevention strategy. These decisions would benefit from insight provided by

本书版权归John Wiley & Sons Inc.所有

people involved in the trade, animal health managers, rural development experts, and food system specialists. Nguyen et al. (39), for example, recognized how market interventions can shift rather than eliminate zoonotic disease risk. Others have advised cautious and careful approaches to wildlife market bans to avoid inadvertent conservation and social impacts which may result in undesired nontargeted effects, such as increased illegal and unregulated trade or reduced social benefits from wildlife in vulnerable communities (40–42). Accounting for relationships between people, animals, and environments in epidemiological systems can provide a wider perspective to discover alternative means of solving problems and avoid unintended consequences. This can help people see different aspects of the problem and, by exploring these differences, find solutions that go beyond their own perspective of the problem.

Confronting the Reality of Complexity

Responses to 21st century health threats will be unpredictable and emergent rather than predictable and planned because of accelerating social and environmental change and the complexity of interactions between co-occurring global threats (35). Pandemic planning is complicated by trade-offs between multiple objectives, values, and interests and limited by uncertainties and ambiguities about what causes the emergence and the effects of interventions. There is, therefore, no "recipe book" of predefined management strategies that will work in all situations. Efforts to manage emerging zoonotic disease risks must therefore be adaptive, multifaceted, and multisolving.

Being Multifaceted

Pandemic risk managers cannot escape complex, complicated, and wicked systems. There are physiological systems affecting individual animal and human response to infections, socio-ecological systems affecting population vulnerability, governance systems that affect how we make decisions and work together, surveillance systems affecting what patterns we see, regulatory and social systems affecting how we value and treat animals, and ecosystems on which we all depend. Each of these systems has fuzzy boundaries, so that they spill over and affect each other. Changes in ecological systems caused by multifaceted interactions with social system changes produce feedbacks that affect natural communities and ultimately their pathogen, animal host, and human populations (43). Knowledge about new threats and risk factors alone will not lead to risk reduction without also recognizing and understanding the factors that shift a socio-ecological system to a safer state. Achieving optimal pandemic preparedness lies as much in understanding the circumstances of disease emergence as it does in understanding the biological hazards that cause the disease. Without transformation to address root causes of disease emergence and resilience, we will continue to battle new crises as they emerge.

Well-rounded decision making and smarter, better interventions benefit from inclusion of contextual information derived from multisectoral learning and practices (44). While whole-of-society approaches to pandemic preparedness recognize the importance of working beyond the health sector, they generally do not place society within its wider ecosystem, thus neglecting the ecological relationships that underpin community resilience or drive disease emergence. The onset of the Anthropocene has meant that we can no longer ignore the relation between people, the environments they inhabit, and the animals on which they depend (45). Future pandemic planners will, therefore, need to come from within and from outside the health professions and be adept at crossing boundaries.

One Health offers a guiding philosophy to bridge and integrate disciplinary silos which have separated the study of human disease from the study of nonhuman disease and ecological concerns (46). Unfortunately, implementing a One Health approach in an integrated and considered manner faces sociopolitical, ethical, and legal challenges (46). Recent attention to One Health at high-level political fora has increased power struggles between dominant stakeholders, in a context where investment in collaboration building is lacking (47). There has been a boon in recent publications calling for systemic change to promote One Health approaches and for program evaluations to better understand what One Health projects work, how they work, where, and for whom (for examples, see references 48, 49, and 50).

Being Multisolving

Being ready for surprises means supporting health early rather than only controlling disease later. The goal of an action-oriented One Health approach is not to build more and more complex models to predict the next hazard, but rather to build robustness against negative events that occur. Health is a multisolving resilience-building tool because healthy populations are resilient to a wide suite of disturbances, disasters, and threats. Healthy livestock, for example, are a key asset that helps many communities, including some of the world's most vulnerable, deal with a changing and uncertain future. Empowering communities to protect and promote animal health and welfare improves livelihoods while building resilience to endemic and emerging threats (51). A livestock health promotion program therefore not only can reduce the likelihood of zoonotic diseases in source animals and reduce the use of antimicrobials in those animals but also can make livestock owners healthier and more resilient against the effects of an emerging disease. In this example, livestock health is a multisolving solution.

By leveraging One Health collaboration, it is possible to design and implement projects that improve public health,

本书版权归John Wiley & Sons Inc.所有

protect animal determinants of human health (such as food security and incomes), and promote biodiversity conservation simultaneously. An interspecies and intergenerational approach to pandemic preparedness and response increases the chances of collaboration and investment by addressing the needs of multiple partners required to combat and prevent pandemics and by creating economic efficiencies by having the cross-sector benefits of investment. Strong interdisciplinary partnerships are now reaching revolutionary tipping points to better understand the multilevel "causes of the causes" and to identify acceptable and sustainable multisolving solutions (52).

Management objectives that rely heavily on maintaining the status quo or reverting to historical rates of emerging diseases, rather than promoting resilience against the unexpected, will need to be reevaluated considering climate disruption and other environmental trends that are driving emerging disease risks in surprising ways. Changes in land use, food systems, and livelihoods are occurring so rapidly that there are no set routes for successful adaptation for the future (53). If we remain fixated on discovering the "scientific laws of health" to predict a problem rather than building resilience against the next inevitable unknown problem, we get farther behind. The COVID-19 pandemic was a stark reminder of the critical need for governments to be agile and adaptive in the face of a changing knowledge landscape.

Being Adaptive

Adaptive management "is intended to increase the ability to fashion timely responses in the face of new information and in a setting of varied stakeholder objectives and preferences" (54). Adaptive management in a One Health context has been useful in ensuring successful and long-lasting positive outcomes for all sectors of society, including animal and human populations (55). Governments and communities must be able to assess their circumstances across sectors, learn from each other's pandemic and emerging disease experiences, and adjust their strategies considering a new normal brought about by a pandemic. Adaptive management is enabled by incorporating different knowledge systems and stakeholder viewpoints (55). It requires collaborations to characterize the full extent of a problem, anticipate the possible consequences of responses throughout the system being managed, evaluate impacts of interventions, and incorporate lessons learned into future decisions (56).

SUMMARY

Transformative changes are needed in how we approach human-animal-environment relationships and their codependence for health. Decision makers aspiring to manage pandemic impacts, adaptation, and vulnerability in the Anthropocene need a wide range of information drawing from many disciplines. Policies and actions must be crafted with the larger framework in mind and consider the impacts, trade-offs, and synergies that can occur across different aspects of a shared problem.

There are four pillars to being ready for the Anthropocene (57–59). The first is to recognize the interdependence of human and nonhuman systems in health protection, human development, and conservation policies and programs. The second is the need for multifaceted approaches that address problems concurrently from several perspectives for faster, more effective impacts that are acceptable and sustainable. The third is collaborative and cross-sectoral learning that makes the best use of limited resources by sharing ideas, innovations, information, resources, and expertise to combat threats that concurrently impact multiple sectors and species. The fourth is to shift away from vertical (problem- or disease-specific) to horizontal (comprehensive) solutions.

Although existing science cannot prescribe a generalizable emerging disease strategy, One Health action can be helpful to (i) identify and address social, animal, ecological, and health drivers that are conducive to disease emergence and increase vulnerability to their effects; (ii) proactively build capacity for people and animals to cope with multiple interacting threats and stressors to reduce vulnerability and build resilience against emerging disease; (iii) develop capacity to adaptively respond to surges in unexpected diseases or disease outbreaks; (iv) integrate emerging disease activities into animal health, public health and ecosystem management; (iv) investigate and communicate the implications of emerging disease for animal health, conservation, food security, public health, and community resilience to encourage political and multisectoral collaboration; and (vi) develop innovative leadership, partnerships, and governance that support cross-sectoral, collaborative actions.

KEY POINTS

- Pandemic risk managers can no longer assume that historic approaches to risk reduction will be suited to a "new normal" world inundated by climate change, biodiversity loss, landscape alterations, and increasing connectivity.
- Optimal pandemic preparedness lies as much in understanding the upstream circumstances of disease emergence as in understanding the biological hazards that cause the disease, but the lack of information and disconnected efforts across organizations researching and managing human, animal, and environmental health constrains attempts to systematically and routinely do so.
- In the face of uncertainty and ambiguity about the course of pandemic risks, the goal is not only to build

本书版权归John Wiley & Sons Inc.所有

more complex models to predict the next hazard by integrating animal and environmental data but also to build robustness against negative events that occur by creating resilience through interspecies and intergenerational health equity.

- One Health offers a guiding philosophy to bridge and integrate disciplinary silos which have separated the study of human disease from the study of nonhuman disease and ecological concerns.
- An interspecies and intergenerational approach to pandemic preparedness and response increases the chances of collaboration and investment by addressing the needs of multiple partners required to combat and prevent pandemics and by creating economic efficiencies by having cross-sector benefits of investment.

GLOSSARY

Anthropocene Proposed name for the current geological age, during which human activity has been the dominant influence on climate and the environment.

Complicated system System that can be (dis)assembled and understood as the sum of its parts.

Complex adaptive system System composed of heterogeneous parts, each of which is affected by its own decisions and circumstances. The parts interact with one another in synergistic, antagonistic, or neutral feedbacks, thus influencing each other as well as the behavior of the system. These interactions can lead to unpredictable and emerging situations that are more than the sum of the individual parts. The whole system cannot be understood simply by looking at its individual parts.

Global health security Proactive and reactive steps to minimize events that endanger people's health across geographical regions and international boundaries, wherever they occur in the world.

Intelligence Integration of diverse information compiled, analyzed, and/or disseminated to more rapidly or efficiently anticipate, prevent, or monitor heath threats with the specific aim of inspiring timely and effective action.

Interspecies and intergenerational health equity Circumstances wherein the actions to protect the health of one species or generation do not impede the ability of other species or generations to secure their needs for healthy lives.

Invasive species A species that is nonnative (often introduced by people) to the ecosystem and whose introduction causes or is likely to cause economic or environmental harm or harm to human health.

Landscape The combination of geological, geomorphological, biological, and cultural layers in a location that have evolved over time, as perceived, portrayed, and valued by people.

Livestock Domesticated animals that are raised to provide a diverse array of goods, such as meat, milk, eggs, hides, fibers, and feathers, as well as services.

Pandemic preparedness Ability to prevent, detect, and rapidly respond to pandemics. Preparedness consists of a set of measures undertaken in advance by governments, organizations, communities, or individuals to better respond and cope with the medical, socio-economic, and personal aftermaths of a pandemic.

Pathognomonic Characteristic or indicative of a particular disease or condition.

Population health Programs and activities to improve the health of the entire population and to reduce health inequities by acting upon the broad range of socio-ecologic factors and conditions that have a strong influence on our health.

Resilience The capacity for and process of successfully adapting to difficult or challenging life experiences.

Socio-ecological model of health Socioecological, multilevel conceptualization of health that includes interpersonal, organizational, environmental, and public policy determinants that affect health, wherein health includes access to the needs for daily living, the capacity to cope with stress and change, and ability to meets expectations for life.

Surveillance Ongoing, systematic collection, analysis, and interpretation of health-related data essential to supporting decisions on planning, implementation, and evaluation of health actions.

Tipping point The point at which a series of small changes becomes significant enough to cause a larger, more important change.

Transformative In such as way as to bring about big improvements (in contrast to doing a little more or less of something already being done).

Upstream determinants of health Macrofactors that exert socio-ecological influences on health and health systems, government policies, and the social, physical, economic, and environmental factors that determine health.

Vulnerability The state determined by interactions of exposure, sensitivity, resistance, and resilience to a threat.

Wicked system System wherein problems are difficult or even impossible to tackle by defining optimal solutions because of deep uncertainty, high complexity, and conflicting stakeholder values. Interactions in the system are cross-scale, multilevel, and extremely difficult to identify due to system dynamics and nonlinear interactions. The problems span boundaries, resulting in stakeholders bringing different perspectives to the definitions and potential resolution of the issue.

REFERENCES

1. **Stikeleather J**, **Masys AJ**. 2020. Global health security innovation, p 387–425. *In* Masys AJ, Izurieta R, Ortiz MR (ed), *Global Health Security*. Springer, Cham, Switzerland.

2. **Stephen C.** 2020. Rethinking pandemic preparedness in the Anthropocene. *Healthc Manage Forum* **33**:153–157.

3. **Whitmee S**, **Haines A**, **Beyrer C**, **Boltz F**, **Capon AG**, de **Souza Dias BF**, **Ezeh A**, **Frumkin H**, **Gong P**, **Head P**, **Horton R**, **Mace**

本书版权归John Wiley & Sons Inc.所有

GM, Marten R, Myers SS, Nishtar S, Osofsky SA, Pattanayak SK, Pongsiri MJ, Romanelli C, Soucat A, Vega J, Yach D. 2015. Safeguarding human health in the Anthropocene epoch: report of The Rockefeller Foundation-Lancet Commission on planetary health. *Lancet* **386**:1973–2028.

4. Kareiva P, Fuller E. 2016. Beyond resilience: how to better prepare for the profound disruption of the Anthropocene. *Glob Policy* **7**:107–118.

5. Gross M. 2019. The paradox of the unexpected: normal surprises and living with nonknowledge. *Environment* **61**:20–25.

6. Aragrande M, Canali M, Bouwknegt M, Cornelsen L. 2015. Policy evaluation: a One Health approach: Maurizio Aragrande. *Eur J Public Health* **25**(Suppl 3):ckv170–ckv030.

7. Grogan LF, Berger L, Rose K, Grillo V, Cashins SD, Skerratt LF. 2014. Surveillance for emerging biodiversity diseases of wildlife. *PLoS Pathog* **10**:e1004015.

8. Bedford J, Farrar J, Ihekweazu C, Kang G, Koopmans M, Nkengasong J. 2019. A new twenty-first century science for effective epidemic response. *Nature* **575**:130–136.

9. Kock R, Queenan K, Garnier J, Rosenbaum Nielsen L, Buttigieg S, De Meneghi D, Holmberg M, Zinsstag J, Rüegg S, Häsler B. 2018. Health solutions: theoretical foundations of the shift from sectoral to integrated systems, p 22–37. *In* Rüegg SR, Häsler B, Zinsstag J (ed), *Integrated Approaches to Health: A Handbook for the Evaluation of One Health*. Wageningen Academic Publishers, Wageningen, Netherlands.

10. Fried LP, Piot P, Frenk JJ, Flahault A, Parker R. 2012. Global public health leadership for the twenty-first century: towards improved health of all populations. *Glob Public Health* **7**(Suppl 1):S5–S15.

11. Rabinowitz PM, Pappaioanou M, Bardosh KL, Conti L. 2018. A planetary vision for one health. *BMJ Glob Health* **3**:e001137.

12. Stephen C. 2020. Whose health?, p 17–34. *In* Stephen C (ed), *Animals, Health, and Society*. CRC Press, Boca Raton, FL.

13. Minary L, Alla F, Cambon L, Kivits J, Potvin L. 2018. Addressing complexity in population health intervention research: the context/intervention interface. *J Epidemiol Community Health* **72**:319–323.

14. Kuiken T, Leighton FA, Fouchier RA, LeDuc JW, Peiris JS, Schudel A, Stöhr K, Osterhaus AD. 2005. Public health. Pathogen surveillance in animals. *Science* **309**:1680–1681.

15. Reif JS. 2011. Animal sentinels for environmental and public health. *Public Health Rep* **126**(Suppl 1):50–57.

16. Stephen C, Duncan C. 2017. Can wildlife surveillance contribute to public health preparedness for climate change? A Canadian perspective. *Clim Change* **141**:259–271.

17. Halliday JE, Meredith AL, Knobel DL, Shaw DJ, Bronsvoort BMDC, Cleaveland S. 2007. A framework for evaluating animals as sentinels for infectious disease surveillance. *J R Soc Interface* **4**:973–984.

18. Beeby A. 2001. What do sentinels stand for? *Environ Pollut* **112**:285–298.

19. Dominey-Howes D. 2018. Hazards and disasters in the Anthropocene: some critical reflections for the future. *Geosci Lett.* **5**:1–5.

20. Vrbova L, Stephen C, Kasman N, Boehnke R, Doyle-Waters M, Chablitt-Clark A, Gibson B, FitzGerald M, Patrick DM. 2010. Systematic review of surveillance systems for emerging zoonoses. *Transbound Emerg Dis* **57**:154–161.

21. Stephen C, Berezowski J, Pedro Carmo L, de las Nieves Montano Valle D, Friker B, Alves de Sousa DM, Vidondo B. 2021. A rapid review of evidence on managing the risk of emerging diseases in the wildlife trade. https://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/WGWildlife/OIE_review_wildlife_trade_March2021.pdf. Accessed 9 August 2021.

22. Lessler J, Azman AS, McKay HS, Moore SM. 2017. What is a hotspot anyway*? Am J Trop Med Hyg* **96**:1270–1273.

23. Plowright RK, Eby P, Hudson PJ, Smith IL, Westcott D, Bryden WL, Middleton D, Reid PA, McFarlane RA, Martin G, Tabor GM. 1798. 2015. Ecological dynamics of emerging bat virus spillover. *Proc R Soc Lond B Biol Sci* **7**:20142124.

24. Becker DJ, Washburne AD, Faust CL, Pulliam JRC, Mordecai EA, Lloyd-Smith JO, Plowright RK. 2019. Dynamic and integrative approaches to understanding pathogen spillover. *Philos Trans R Soc Lond B Biol Sci* **374**:20190014.

25. Narat V, Alcayna-Stevens L, Rupp S, Giles-Vernick T. 2017. Rethinking human–nonhuman primate contact and pathogenic disease spillover. *EcoHealth* **14**:840–850.

26. Lloyd-Smith JO, George D, Pepin KM, Pitzer VE, Pulliam JR, Dobson AP, Hudson PJ, Grenfell BT. 2009. Epidemic dynamics at the human-animal interface. *Science* **326**:1362–1367.

27. Cross PC, Prosser DJ, Ramey AM, Hanks EM, Pepin KM. 1782. 2019. Confronting models with data: the challenges of estimating disease spillover. *Philos Trans R Soc Lond B Biol Sci* **374**:20180435.

28. Kreuder Johnson C, Hitchens PL, Smiley Evans T, Goldstein T, Thomas K, Clements A, Joly DO, Wolfe ND, Daszak P, Karesh WB, Mazet JK. 2015. Spillover and pandemic properties of zoonotic viruses with high host plasticity. *Sci Rep* **5**:14830.

29. Davidson PM. 2016. Rockefeller Foundation-Lancet Commission report: a call to action for human health. *Int J Nurs Stud* **53**:1–2.

30. Bradley CA, Altizer S. 2007. Urbanization and the ecology of wildlife diseases. *Trends Ecol Evol* **22**:95–102.

31. Brearley G, Rhodes J, Bradley A, Baxter G, Seabrook L, Lunney D, Liu Y, McAlpine C. 2013. Wildlife disease prevalence in human-modified landscapes. *Biol Rev Camb Philos Soc* **88**:427–442.

32. Daszak P, Cunningham AA, Hyatt AD. 2001. Anthropogenic environmental change and the emergence of infectious diseases in wildlife. *Acta Trop* **78**:103–116.

33. Han BA, Drake JM. 2016. Future directions in analytics for infectious disease intelligence: toward an integrated warning system for emerging pathogens. *EMBO Rep* **17**:785–789.

34. Polasky S, Carpenter SR, Folke C, Keeler B. 2011. Decision-making under great uncertainty: environmental management in an era of global change. *Trends Ecol Evol* **26**:398–404.

35. Hanlon P, Carlisle S. 2008. Do we face a third revolution in human history? If so, how will public health respond? *J Public Health (Oxf)* **30**:355–361.

36. Parker CF, Stern EK. 2002. Blindsided? September 11 and the origins of strategic surprise. *Polit Psychol* **23**:601–630.

37. Galaz V, Moberg F, Olsson E, Paglia E, Parker C. 2011. Institutional and political leadership dimensions of cascading ecological crises. *Public Adm* **89**:361–380.

本书版权归John Wiley & Sons Inc.所有

38. Amman BR, Carroll SA, Reed ZD, Sealy TK, Balinandi S, Swanepoel R, Kemp A, Erickson BR, Comer JA, Campbell S, Cannon DL, Khristova ML, Atimnedi P, Paddock CD, Crockett RJ, Flietstra TD, Warfield KL, Unfer R, Katongole-Mbidde E, Downing R, Tappero JW, Zaki SR, Rollin PE, Ksiazek TG, Nichol ST, Towner JS. 2012. Seasonal pulses of Marburg virus circulation in juvenile Rousettus aegyptiacus bats coincide with periods of increased risk of human infection. *PLoS Pathog* **8**:e1002877.

39. Nguyen TTT, Fearnley L, Dinh XT, Tran TTA, Tran TT, Nguyen VT, Tago D, Padungtod P, Newman SH, Tripodi A. 2017. A stakeholder survey on live bird market closures policy for controlling highly pathogenic avian influenza in Vietnam. *Front Vet Sci* **4**:136.

40. Rivalan P, Delmas V, Angulo E, Bull LS, Hall RJ, Courchamp F, Rosser AM, Leader-Williams N. 2007. Can bans stimulate wildlife trade? *Nature* **447**:529–530.

41. Roe D, Dickman A, Kock R, Milner-Gulland EJ, Rihoy E, 't Sas-Rolfes M. 2020. Beyond banning wildlife trade: COVID-19, conservation and development. *World Dev* **136**:105121.

42. Santos A, Satchabut T, Vigo Trauco G. 2011. Do wildlife trade bans enhance or undermine conservation efforts. *Appl Biodiv Perspect Ser* **1**:1–5.

43. Finucane ML, Fox J, Saksena S, Spencer JH. 2014. A conceptual framework for analyzing social-ecological models of emerging infectious diseases, p 93–109. *In Understanding Society and Natural Resources*. Springer, Dordrecht, Netherlands.

44. Armstrong R, Doyle J, Lamb C, Waters E. 2006. Multi-sectoral health promotion and public health: the role of evidence. *J Public Health (Oxf)* **28**:168–172.

45. Ramos G, Hynes W, Müller JM, Lees M. 2019. *Systemic Thinking for Policy Making: The Potential of Systems Analysis for Addressing Global Policy Challenges in the 21st Century*. OECD Publishing, Paris, France. https://www.oecd.org/naec/averting-systemic-collapse/SG-NAEC(2019)4_IIASA-OECD_Systems_Thinking_Report.pdf. Accessed 9 August 2021.

46. Degeling C, Johnson J, Kerridge I, Wilson A, Ward M, Stewart C, Gilbert G. 2015. Implementing a One Health approach to emerging infectious disease: reflections on the socio-political, ethical and legal dimensions. *BMC Public Health* **15**:1307.

47. Spencer J, McRobie E, Dar O, Rahman-Shepherd A, Hasan N, Hanefeld J, Khan M. 2019. Is the current surge in political and financial attention to One Health solidifying or splintering the movement? *BMJ Glob Health* **4**:e001102.

48. Häsler B, Cornelsen L, Bennani H, Rushton J. 2014. A review of the metrics for One Health benefits. *Rev Sci Tech* **33**:453–464.

49. Khan MS, Rothman-Ostrow P, Spencer J, Hasan N, Sabirovic M, Rahman-Shepherd A, Shaikh N, Heymann DL, Dar O. 2018. The growth and strategic functioning of One Health networks: a systematic analysis. *Lancet Planet Health* **2**:e264–e273.

50. Lee K, Brumme ZL. 2013. Operationalizing the One Health approach: the global governance challenges. *Health Policy Plan* **28**:778–785.

51. Njisane YZ, Mukumbo FE, Muchenje V. 2020. An outlook on livestock welfare conditions in African communities—a review. *Asian-Australas J Anim Sci* **33**:867–878.

52. Mabry PL, Olster DH, Morgan GD, Abrams DB. 2008. Interdisciplinarity and systems science to improve population health: a view from the NIH Office of Behavioral and Social Sciences Research. *Am J Prev Med* **35**(Suppl):S211–S224.

53. Jackson L, van Noordwijk M, Bengtsson J, Foster W, Lipper L, Pulleman M, Said M, Snaddon J, Vodouhe R. 2010. Biodiversity and agricultural sustainagility: from assessment to adaptive management. *Curr Opin Environ Sustain* **2**:80–87.

54. NRC. 2004. Adaptive management for water resources project planning. National Academies Press. https://www.nap.edu/read/10972/chapter/4. Accessed 9 August 2021.

55. Shury TK, Brook RK, Nihal PD. 2020. Managing zoonotic disease in wildlife populations: priorities and pitfalls of the human connection, p 245–254. *In* Stephen C (ed), *Animals, Health, and Society*. CRC Press, Boca Raton, FL.

56. Ebi K. 2011. Climate change and health risks: assessing and responding to them through 'adaptive management'. *Health Aff (Millwood)* **30**:924–930.

57. Bali S, Taaffe J. 2017. The sustainable development goals and the global health security agenda: exploring synergies for a sustainable and resilient world. *J Public Health Policy* **38**:257–268.

58. Berkes F. 2017. Environmental governance for the Anthropocene? Social-ecological systems, resilience, and collaborative learning. *Sustainability (Basel)* **9**:1232.

59. Stephen C, Berezowski J, Misra V. 2015. Surprise is a neglected aspect of emerging infectious disease. *EcoHealth* **12**:208–211.

本书版权归John Wiley & Sons Inc.所有

52

Introduction

Perspectives from Previous Pandemics and COVID-19

Investments in Novel Therapeutics • A Progression in Understanding the Evolution of Pandemics • Pandemic Fatigue • Role for Immunology-Based Diagnostics • Early Recognition—SARS-CoV-2 and Its Global Spread • Emergence of COVID-19 and the Response of Taiwan • Effective Mitigative Solutions for COVID-19 in Taiwan • Paradigm Shift: Roles for Big Data in Pandemic Management

Challenges Facing Clinical and Public Health Laboratories

Roles of Laboratories • Advances in Diagnostic Technology • Genomics and Its Role in Mitigating Pandemics • Microbes to Pandemic Agents: Laboratory Mobilization

Pandemic Planning: Partnerships for the Future

Collaboration between Clinical and Public Health Laboratories • Global Surveillance • Economic Costs • Vaccines • Vaccine Hesitancy • Collaboration and Linkage of Laboratories to Incident Commands • The Next Pandemic for Humankind

SUMMARY

KEY POINTS

GLOSSARY

REFERENCES

Pandemic Planning: Roles of Clinical and Public Health Laboratories

Robert T. Ball, Jr., Joseph F. John, Jr., and Michael G. Schmidt

OBJECTIVES

To list past and current pathogens of pandemics with commentary on laboratory methodologies

To describe the roles and importance of laboratories throughout a pandemic

To summarize the key collaborative roles of laboratories, public health partners, academicians, clinicians, societal leaders, and others to prepare for future pandemics

To articulate some of the collaborative roles of each of these critical functions in pandemic planning partnerships

Chance favors only the prepared mind.

Louis Pasteur (1822–1895) (1)

We live in a world fraught with risk from new pandemics. Fortunately we also now live in an era with the tools to build a global immune system.

Nathan Wolfe (2)

The discovery of viruses by laboratory researchers in the late 19th century represented the culmination of years of work by Mayer, Iwanovsky, and Beijerinck, with their descriptions of the tobacco mosaic virus commencing in 1892 through 1898 (3). Over decades, their discovery led to a paradigm shift in scientific strategy, since it conflicted with the prevailing dogma of the time (Koch's postulates [4]). The appreciation of the infectious nature of "filterable agents" opened a novel and rapidly expanding laboratory discipline. Since then, novel discoveries regarding biological diversity, augmented by ever more sophisticated technologies, have elevated our laboratories to a unique scientific pinnacle in modern medical sciences.

For 150 years, basic sciences and clinical microbiology laboratories together have played a key role in identifying and tracking emerging and reemerged pathogens distressing the human race. Clinical laboratories are usually the first to detect, and ultimately isolate, a new or reemerged pathogen. Detection of the pathogen may result from classic methods involving culture or microscopy or from newer detection methods involving molecular characterization, taking advantage of techniques based on PCR, metagenomics, whole-genome

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch52.

本书版权归John Wiley & Sons Inc.所有

sequencing (WGS), rapid antigen testing, proteomics, microbiome arrays, and others. Four decades of combating the spread of the human immunodeficiency virus (HIV) has primed scientific communities for the use of advanced microbiologic methodologies to understand and control pandemics (5, 6). These methods have opened a new field for real-time data aggregation and its analysis, including an extension for data manipulation (big data) by artificial intelligence (AI) (for reviews and opportunities see references 7–14).

Further, the world's biological diversity, especially in our current Anthropocene era, is considered a potential root source of most pandemics (e.g., HIV-AIDS [15, 16], pandemic influenza [17], severe acute respiratory syndrome [SARS], Middle East respiratory syndrome [MERS] [18], and now coronavirus disease 2019 [COVID-19], Nipah [19], Zika [20], and others). Most experts consider the origin of these pathogens, especially the viruses, to be zoonoses jumping to humans from other species of animals. This movement of zoonotic infections into humans is usually driven by biological, ecological, or human behavioral and socio-economic changes. Unfortunately, despite our advances and better understanding of microorganisms, no pathogen has been identified or predicted before the emergence of its pandemic.

Most infectious diseases infect individuals; outbreaks and epidemics affect larger numbers of the population. By definition, a pandemic is a global epidemic, where the pathogen crosses international borders (today, usually as a consequence of air travel). A truism of pandemics is that if you are not infected, you are affected.

In the century since Pasteur, Koch, and Beijerinck, laboratory research with increasingly novel discoveries, augmented by ever more sophisticated technologies and facilitated by interdisciplinary collaborations, has elevated the capabilities of laboratories to their current scientific pinnacle, where it is now possible to design and produce a viable vaccine within weeks of an emergence of a new virus (21, 22).

Laboratory analysis of the microbes responsible for some of the most significant epidemics and pandemics of the last 5 centuries has triggered much of our understanding of the pathogenesis of infectious agents. Insight gained from past pandemics has advanced our abilities to first identify and then develop treatments and prevention modalities to lessen their severity, duration, and frequency.

In this chapter, we discuss aspects of previous pandemic pathogens, the challenges and solutions they presented, and the current COVID-19 pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), for which we will highlight lessons learned and how this information can aid in pandemic planning of the future.

Perspectives from Previous Pandemics and COVID-19

Today's laboratory professionals, using modern diagnostic tools, have usually been the first to detect the next and often novel emergence of an epidemic or pandemic pathogen but often among the last to get credit for their discoveries. This is especially true today with the emergence of a novel coronavirus responsible for what we now appreciate as the COVID-19 pandemic. The agent implicated in the pandemic, SARS-CoV-2, is closely related to another coronavirus, the severe acute respiratory syndrome virus of 2003. SARS-CoV-2 is responsible for the worst pandemic and subsequent global crisis since the early 20th century. Of late, investigators have worked ceaselessly in their development of novel techniques and testing strategies, vaccines, and therapeutics in order to slow the spread of this agent. Many of their efforts were based on what was learned from previous pandemics and the responsible infectious agents.

Investments in Novel Therapeutics

Smallpox, the premier prototypic pandemic plague of *Homo sapiens* for unknown millennia, is of uncertain origin but had devastated the global population with hundreds of millions of deaths by the 20th century (the highest mortality of any pandemic). In spite of this lethal pandemic agent having been eradicated globally, smallpox continues to garner attention in the scientific community (23, 24). In this decade alone, two new antivirals were approved for use to treat this extinct virus. Brincidofovir, approved in 2021, a lipid conjugate of cidofovir, has good bioavailability and may be useful for treating other serious diseases or conditions caused by other double-stranded DNA viruses (25–27). Tecovirimat, approved in 2018, has antiviral activity against orthopoxviruses such as smallpox virus and another potential virus of concern, monkeypox or the Mpox virus (28, 29). One may ask why we would go through the expense of developing a drug for an extinct virus. Simply, this is done to address the need to develop antivirals that could then be used to treat other double-stranded viruses. Today, we know that laboratories need to remain vigilant and be able to differentiate the biothreat agent smallpox virus from the zoonotic facsimile virus monkeypox virus (30, 31). Having an antiviral that can be used to control its spread offers healthcare an opportunity to prevent zoonotic viruses from better adapting to a human host.

A Progression in Understanding the Evolution of Pandemics

Although *Homo sapiens* had been plagued by influenza pandemics for centuries, the pandemic influenza of 1917 to 1919 differed in several novel ways. First, there were no

本书版权归John Wiley & Sons Inc.所有

laboratory or clinical methodologies to diagnose the viral etiology in 1918. Second, the unique W-shaped mortality curve contrasted dramatically with curves in other epidemics and pandemics in that deaths were occurring not only among the very old and very young but also among supposedly healthy people in their 20s and 30s. Third, laboratories and medical science in the early 20th century struggled to differentiate medically primary influenza from secondary bacterial pneumonia. Fourth, the pandemic of 1917 to 1919 now serves as the prototype of "spillover" infections, communicable diseases which transfer (via various modes) from other animals to humans.

While it unknown whether the 1918 H1N1 strain of influenza virus mutated into other variants of concern during its pandemic, the incidence of H1N1 infection declined and herd immunity developed as basic public health interventions were implemented. During the fall of 1918, the incidence of infections in the United States briefly receded before surging again at the end of the year, perhaps fueled by the public's desire to return to normal and by a relaxation of nonpharmaceutical mitigative steps (e.g., wearing masks), or simply as a consequence of public "pandemic fatigue" (32).

Pandemic Fatigue

A similar observation regarding pandemic fatigue was witnessed in the COVID-19 pandemic in the fall of 2021 and winter of 2022 with the result being surges of SARS-CoV-2 variants of concern, Delta and Omicron. The Omicron variant in particular generated morbidity and mortality rates beyond what was witnessed during the initial waves of the pandemic (33). A strategy to control the spread of the new variants, named TETRIS (for "**te**sting, contact **tr**acing, and **is**olation of the infected"), has been advocated to help control the spread of new infections in hopes of limiting the emergence of another variant. This strategy was needed despite the availability of highly effective and safe vaccines against the virus (34). A TETRIS strategy was deemed necessary given the low penetrance of vaccination in certain areas of the United States and the world. The higher attack rate witnessed for the two variants of concern, Delta, with an estimated basic reproduction number (R_0) of ~5.08, and Omicron, with an estimated R_0 greater than ~7.0 (35), was significant. The original variant of SARS-CoV-2 was estimated to have an R_0 of ~2.79 (35). As a result of the surge of the SARS-CoV-2 Delta/Omicron variants, laboratories saw a dramatic surge in the need for diagnostic testing. Variants continue to emerge as the pandemic subsides, even as we go to press.

On the control side, Janet Woodcock, the acting commissioner of the U.S. Food and Drug Administration (FDA), in testimony before the United States Senate Committee on Health, Education, Labor, and Pensions, stated that Roche and Siemens would make available approximately 400 million at-home tests on a monthly basis to the American public and that Abbott, iHealth Lab, and Roche would provide a combined 380 million over-the-counter antigen test kits to the Department of Defense in support of its testing needs (34). While convenient, home testing often lacks the seamless integration of the results from the performed tests into common data warehouses. The lack of aggregation of home testing data raises the question of whether the expense incurred by society from such in-home testing is justified by its role in accurately informing public health decisions.

Role for Immunology-Based Diagnostics

The origin of HIV almost certainly occurred in the mid-20th century, as evidenced by laboratory testing of stored blood and tissue obtained prior to this time showing no evidence of HIV antibodies or genetic material prior to the mid-1900s (36, 37). The major 20th-century laboratory contributions to novel HIV discoveries have extended to the development of a substantial body of literature regarding the social, societal, preventive, therapeutic, and scientific determinants of HIV and AIDS (5, 37). While the HIV pandemic persists, the efforts in controlling this pandemic have paid dividends in our efforts to control SARS-CoV-2. Many of these are appreciated in the technologies used to develop molecular and immunology-based diagnostics to detect the incidence of SARS-CoV-2 within communities.

In spite of advances in immunodiagnostics for HIV, the FDA cautioned public health departments and healthcare providers that results from SARS-CoV-2 antibody tests with current emergency use authorizations (EUA) should not be used to evaluate a person's level of immunity or protection from COVID-19 at any time, especially after the person received a COVID-19 vaccination (38). In a review of the literature conducted in the Cochrane COVID-19 Study Register and the COVID-19 Living Evidence database from the University of Bern, the authors concluded there may be a role for antibody tests. They suggested that they were uncertain about the utility of tests used for seroprevalence surveys for the management of public health decisions (39). Work continues to bring SARS-CoV-2-specific T-cell-based assays into clinical and public health laboratories. As of this writing, they are not ready for widespread deployment.

Early Recognition—SARS-CoV-2 and Its Global Spread

In fall of 2019, Chinese scientists reported a mysterious fatal respiratory illness in Wuhan and reported another novel coronavirus as the probable cause, now named SARS-CoV-2, a pathogen whose origin is currently in more political than scientific dispute. In February 2020, an early notice appeared in the *Journal of Clinical Infectious Diseases* (40).

本书版权归John Wiley & Sons Inc.所有

Chinese laboratory scientists using released sequence data on the virus, then known as 2019-nCoV, conducted phylogenomic analysis and offered that the emergent virus was most closely related to two SARS-like CoV sequences previously isolated from viruses found in bats in 2015–2017, suggesting that bat CoV and human 2019-nCoV (SARS-CoV-2) shared a recent common ancestor (40).

Although it was originally thought to be similar to the common cold virus, by the first quarter of 2020, it was evident that SARS-CoV-2 was a novel pathogen with pandemic potential. Unlike its most similar coronavirus relative, SARS-CoV-1, SARS-CoV-2 continues to demonstrate novelty through its ever-changing transmission dynamics associated with its many variants. Data published in 2020 and 2021 suggested an average R_0 of >3 to 5. The Centers for Disease Control and Prevention (CDC) noted in 2021 that the Delta variant likely has an R_0 more like that of the varicella (chickenpox) virus (i.e., 10 to 12). In the fall of 2021, the University of Washington Institute for Health Metrics and Evaluation (IHME) model suggested use of the real-world transmission rate (R_t) in order to better understand the transmission dynamics of the virus. Each time SARS-CoV-2 replicates, there is an opportunity for the development of a new variant that has the potential to escape the PCR primers used in current laboratory diagnostics. Using sophisticated mathematical modeling in summer of 2021, the R_t was reported to be approximately 1.0 to 1.5. However, the Delta variant showed a higher transmissibility, with R_t values above 2 by late fall 2021. Then, in November 2021, the novel Omicron variant appeared globally and spread rapidly. Laboratory WGS revealed that it had at least 50 mutations, 30 more than Delta. More laboratory-identified mutations are likely, but the current PCR primers used in the diagnostic tools are still proving useful.

Emergence of COVID-19 and the Response of Taiwan

Of the many lessons learned from the COVID-19 pandemic, none has been as remarkable, and potentially valuable, as the use of "big data" to control the response to the pending pandemic reaching Taiwan in early 2020. A small island off the coast of China, with a population of 23 million citizens, of whom approximately 5.5% either work or reside in China, Taiwan receives many visitors each year. In the year prior to the emergence of SARS-CoV-2, the island saw a 7% increase in the number of foreign visitors (11.84 million), with approximately 2.7 million traveling from China (41).

In reacting to the pandemic threat from SARS-CoV-2, Taiwan quickly mobilized and instituted an integrated approach of first identifying and containing the virus and then, importantly, allocating resources toward the common goal of ensuring public health by limiting the spread of the virus among the population. Their approach was clever in that they leveraged their national health insurance database with their immigration and customs databases to formulate and deploy a custom data analytic-driven mitigation effort (42). The big-data analytic approach afforded them the ability to quickly generate real-time alerts during a presenting patient's clinical visit based on travel history and clinical symptoms to facilitate case identification and control measures (quarantine and/or isolation).

Effective Mitigative Solutions for COVID-19 in Taiwan

The Taiwanese were also able to use the emerging technologies of QR code scanning and health reporting applications deployed to travelers' mobile phones to facilitate the rapid collection of travel history and health symptoms, from which they were able to stratify the travelers' infection risks based on flight origin and travel history associated with the likely incubation window of the emerging virus (14 days) (42). Persons with low risks, absent travel to areas of high viral transmission or case incidence, were sent a health declaration border pass via their mobile device's text messaging application (SMS), enabling faster immigration clearance; those with travel to higher-risk areas were quarantined at home and tracked through their mobile phone to ensure that they remained sequestered during the incubation period (42).

In the 2 years since the emergence of SARS-CoV-2, Taiwan has been spared the brunt of the many tragedies of the COVID-19 pandemic, having identified only 17,885 cases (0.08% of their population) and recorded a total of 851 deaths on account of the virus (43). As the pandemic ravaged other areas of the world, their continued efficient approach to managing the crisis served them well. Taiwan's approach was based on their experience with another newly emerged pathogen, SARS-CoV-1, in 2003. It was because of this experience that the government knew to employ the principles inherent to the incident command system (ICS) management approach, used to manage natural disasters such as earthquakes, fires, and floods. In 2004, Taiwan established the National Health Command Center (NHCC) (44). This organization serves as the central command center in response to the public health emergencies. In order to achieve its mission, it follows the three I's: initiation, integration, and innovation (44). Shortly after the beginning of the COVID-19 crisis on the mainland was recognized, Taiwan activated four independent centers. They were the Central Epidemic Command Center, the Biological Pathogen Disaster Command Center, the Counter-Bioterrorism Command Center, and the Central Medical Emergency Operations Center (44). Their innovative approach required that the centers collectively focus on developing solutions centrally. By focusing the resources from independent groups, they were able to nimbly respond to the emerging crisis with deliberate and effective

本书版权归John Wiley & Sons Inc.所有

strategies, changing them as an understanding of the virus emerged and thereby safeguarding the health of their citizens.

By mid-February 2020, all hospitals, clinics, and pharmacies in Taiwan had access to the travel history of individuals seeking care. The country effectively communicated the intentions of their mitigative solutions to control the pandemic through real-time communications, ensuring that those contracting the disease were not marginalized by providing food and frequent health checks and encouraging those in quarantine by stating that they were helping to control the severity of the disease (42).

Other nations have similarly developed equivalent NHCCs, culminating in the Joint External Evaluation (JEE), a consolidation of resources and best practices from the World Health Organization (WHO) International Health Regulations 2005 Monitoring and Evaluation Framework and the Global Health Security Agenda country assessment tool exercises (45). Taiwan and other countries that have followed the JEE iterative processes in identifying and filling gaps in addressing the necessary requirements for controlling the outbreak have fared better, as evidenced by the measurement of the incidence of infections and deaths, than countries that have failed to establish partnerships and invest in the necessary infrastructure to react quickly as new information, treatment modalities, and preventive measures (vaccines) have emerged.

Paradigm Shift: Roles for Big Data in Pandemic Management

The elements required to limit the scope and consequence of future pandemics are illustrated in Fig. 52.1. At its base, this systematic approach requires that nations establish some form of universal health coverage, not only to care for their citizens but also to serve as a comprehensive data warehouse from which future pandemics might be forecast and managed. With this approach, in addition to limiting morbidity and mortality, the continuous analysis of deidentified data could serve as an early warning system for public health agencies. It is anticipated that once such a system is triggered, nonpharmaceutical mitigative steps might be introduced early to limit viral spread until such time as pharmacological interventions can be developed and/or deployed.

Infectious disease surveillance in the era of big data is moving toward faster and locally relevant systems (13).

Figure 52.1 Pandemic planning strategy showing elements required to limit the scope and consequences of future pandemics. Each element depicted on the pandemic planning pyramid supports the overall strategy of curtailing the morbidity and mortality of an infectious disease outbreak. The pinnacle of the pyramid acknowledges that despite the best interventions and treatment approaches, without cooperation from the public, efforts to contain a pandemic will be limited.

本书版权归John Wiley & Sons Inc.所有

The use of spatial big data, where decision makers have access to the velocity, volume, and variety of other disparate but relevant big-data sources, including geographical frequencies (9), can aid decision makers in resource allocation and the distribution of critical nonpharmacological supplies and pharmacological interventions. The CDC established such a resource, the COVID Data Tracker (https://covid.cdc.gov/covid-data-tracker/#datatracker-home, accessed 5 September 2023). Here, the agency offers responders, as well as the general public, the latest data concerning the spread of SARS-CoV-2 and its variants from within their communities to the national level. Additionally, they published a short-term forecast, known as Nowcast (https://covid.cdc.gov/covid-data-tracker/#variant-proportions, accessed 5 September 2023), for the anticipated COVID-19 cases and deaths likely to occur, contrasting the effectiveness of their model against cases and deaths observed. Nowcasting has been successfully used to model influenza outbreaks in local (46) and national settings and most recently to evaluate the incidence indicators during the first COVID-19 outbreak in Italy in the spring of 2020 (47).

Challenges Facing Clinical and Public Health Laboratories

Roles of Laboratories

In October 2001, an astute laboratorian in West Palm Beach, FL, quickly recognized anthrax in a spinal fluid Gram stain as highly unusual and wisely called her local public health physician immediately. The public health physician then notified the patient's personal infectious-disease physician the same day, and they were in the laboratory within a few hours to confirm the suspected diagnosis (48). By the end of the day, the CDC was on site, and America's anthrax epidemic quickly unfolded and was quickly arrested. This example illustrates the value and importance of local, state, and regional outpatient laboratories serving as early warning systems in facilitating our recognition of a potential epidemic/pandemic.

Today, laboratory professionals are very familiar with the tools that are rapidly becoming the standard of care used in diagnostic laboratories. However, a significant need that remains is the seamless integration of the data collected locally into regional, national, and international data warehouses and clearinghouses. The information generated from microbiological and molecular tests has been used successfully to facilitate global collaboration in the fields of diagnostics, therapeutics, and vaccine development.

Advances in Diagnostic Technology

While SARS-CoV-2 has caused a devastating pandemic, it has also taught us many lessons for the laboratory as we consider future pandemic planning. The responses to the COVID-19 pandemic exploited molecular techniques that were a consequence of advances made in molecular diagnostics over the last 40 years. These advances paid dividends as the world came to grips with containing the spread of the SARS-CoV-2 (for reviews, see references 49–52).

In the transition to develop a definitive diagnostic test, the WHO initially offered two for emergency use to assess whether an individual was infected with SARS-CoV-2 (53). The tests were developed as a consequence of the rapid release of the complete genome of the virus in early January 2020 and its subsequent publication in March 2020 (54). These first *in vitro* diagnostic tests were granted EUA in order to help nations address the need for testing with quality-assured diagnostics, according to Dr. Mariângela Simão, WHO Assistant-Director General for Medicines and Health Products (53). The emergency use listing procedure (https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic—emergency-use-listing-procedure-eul-open, accessed 5 September 2023) greatly expedited the availability of diagnostics to desperate nations attempting to contain the spread of the virus. These first two EUA tests were just the beginning. As of September 2021, the FDA indicated that there are 235 molecular tests available to detect the presence of viral mRNA, along with 88 antibody tests and 34 antigen tests (55). Of this large number of tests, 63 were suitable for home collection. With them, individuals suspected of being infected could collect their own specimens but were still required to send it to a laboratory for processing (55). Additionally, 32 tests were optimized for testing multiple people at one time. Such pooling methodology is limited in utility to when the percentage of the virus circulating in the community is low (56). Fifty-five of the tests can be classified as point-of-care tests. Additionally, along with the COVID-19-specific tests, 19 multianalyte tests that can detect multiple infectious agents, such as influenza virus and SARS-CoV-2, have been approved for use (55). Finally, as the need for society to return to normal increased, 13 at-home tests were authorized that allowed individuals to perform the tests in their homes with a self-collected sample (55).

Many clinical laboratories have brought next-generation sequencing tools into their facilities, either locally or externally provided through reference laboratories. Nevertheless, it is important to establish funding, sampling strategies, and sampling frequencies so that local clinical laboratories can report to public health agencies the status of the infectious agents circulating in their communities.

Diagnostic laboratories will face an ongoing challenge as SARS-CoV-2 continues to adapt to the human host. In the fall of 2021, developing and developed nations saw the emergence of the Omicron variant, which was capable of causing (57, 58) an increased frequency of breakthrough infections in spite of individuals being fully vaccinated and boosted (59). Hindsight established that this variant was in circulation before it was first reported by the South Africans. In the short time since the emergence of Omicron

本书版权归John Wiley & Sons Inc.所有

and other variants of concern, clinical research and public health laboratories have been at the forefront of these activities (57, 58, 60). The emergence of this variant underscores the need to continuously sequence viral populations in circulation to, at a minimum, ensure the integrity of the diagnostic platforms being employed to limit the spread of the pandemic agent in communities.

Genomics and Its Role in Mitigating Pandemics

SARS-CoV-2 genomic laboratory data have been shared internationally on an unprecedented scale. An excellent example is the widespread availability of SARS-CoV-2 sequence data from the Global Initiative on Sharing Avian Influenza Data (GISAID [www.gisaid.org; accessed 25 April 2022]). Originally developed to share full genomic data on influenza virus strains in 2020, GISAID began transparently sharing the sequences from the pandemic strains of human coronaviruses through this international repository (61–63). In the short period of time since, GISAID has shared over 6 million genome sequence submissions of SARS-CoV-2.

In the last decade, the CDC developed the Advanced Molecular Detection (AMD) program (www.cdc.gov/amd [accessed 25 April 2022]) to integrate the latest next-generation genomic sequencing and WGS technologies with public health bioinformatics and epidemiology expertise. The addition of WGS has moved this multipurpose program into today's spotlight on laboratories. AMD's foci include, but are not limited to, diagnostics (especially discovery of emerging pathogens); identification of viral, bacterial, and fungal pathogens; and genotyping and phenotyping with a new focus on pandemic variants. AMD also includes genomic typing of eukaryotic pathogens and identification of new malaria-causing species.

The AMD program (Fig. 52.2) and others have been using SARS-CoV-2 deep genomic sequencing of the gene region encoding the receptor-binding domain of the virus's spike protein for the presence of novel variants in cities' wastewater (64). As novel cryptic variants are detected in wastewater samples, many of which may not be recognized in GISAID's EpiCoV database, public health agencies could benefit from the advanced warning, as they have been correlated to be predictors of soon-to-follow human COVID-19 outbreaks (64–67). The CDC's AMD program exemplifies a collaborative partnership between laboratory-based genomics and public health agencies to help control and prevent tomorrow's pandemic. CDC AMD is now testing many U.S. wastewater systems to detect early any new SARS-CoV-2 variants (64, 65, 67).

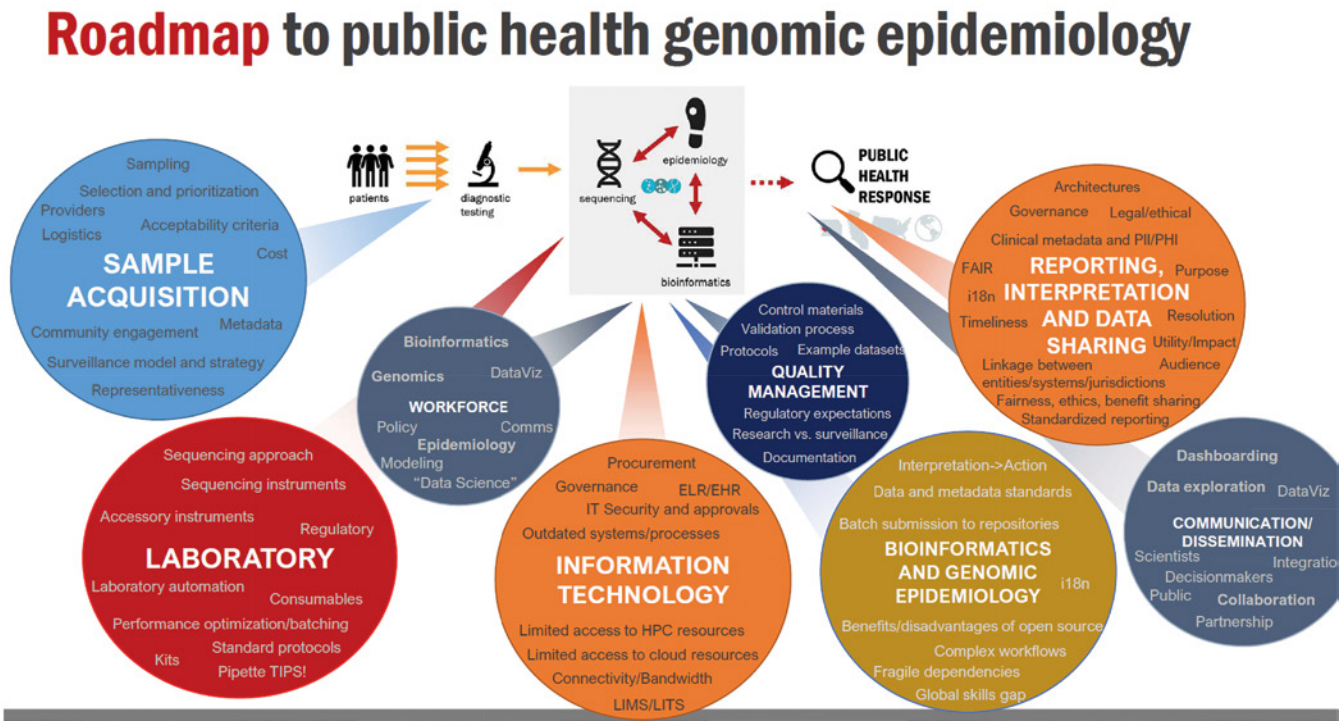


Figure 52.2 Road map to public health genomic epidemiology. AMD public health grand rounds of 2 February 2022. The image illustrates the need for relevant interactions among the disciplines listed to support the emerging field of genomic epidemiology. Genomic epidemiology provides a powerful tool for surveillance, outbreak detection, and response and helps shape a future where genomes of pathogens can direct public health action. Courtesy of Eleanor Click.

本书版权归John Wiley & Sons Inc.所有

Microbes to Pandemic Agents: Laboratory Mobilization

Any rapid spread of a novel or a recurring microorganism must trigger a multiorganizational response. Laboratories must be at the forefront of such an effort and immediately utilize their expertise to identify the type of organism emerging and then, as quickly as possible, determine how best to confine and simultaneously study the emerged pathogen. Part of the problem with COVID-19 was that the very organism being studied in local research laboratories for its infectious potential was emerging in the community as a pandemic infectious agent. Research laboratories dedicated to the study of coronaviruses were in short supply worldwide, speaking perhaps to the value of broad-based research support of laboratories studying novel agents. The genetic sequence of SARS-CoV-2 was released early from a Chinese database, and multiple diagnostic tests and vaccines were developed from this information (see "Vaccines"). Despite the early successes in deploying diagnostic tools and the rapid development, trial, and ultimate availability of multiple effective vaccines, fundamental challenges remain. Diagnostic and research laboratories still need to develop a better approach in their understanding and documenting of the enormous pathogenic potential of SARS-CoV-2.

Multiple institutions exist to respond to a pandemic threat. The two most likely institutions with the widest influence to set policy and global goals are the United Nations (UN) and the WHO. Following the 2002 SARS-CoV-1 pandemic, there was a broadening of international health regulations (IHR) (68). This effort succeeded partially in one goal: to achieve government transparency. Now, nearly two decades later, international cooperation has deteriorated, prompting a need for expansion of the IHR and for bringing divergent laboratories together. Despite the criticism of WHO at the outset of the COVID-19 pandemic, it is hard to envision, under current conditions, how any organization other than the WHO could direct and coordinate worldwide laboratory collaboration in preventing and responding to the next pandemic.

Pandemic Planning: Partnerships for the Future

When Taiwan responded to the emergence of a new and potentially epidemic-causing infectious agent in January 2020, the essence of their strategy was to manage the outbreak through a coordinated multifaceted response, thus limiting the emergence of the epidemic. As seen in Taiwan, this required the timely creation of critical partnerships across a broad swath of government agencies as well among laboratorians, research academicians, clinicians, public health professionals, data scientists, and societal leaders. Proficiency at all levels was required in concert with a fundamental understanding and coordination of the strengths and limitations of the foundational elements specific to each discipline. Recall that at the top of the pandemic strategy pyramid (Fig. 52.1) sits a most crucial element—a need for transparent and proactive communication of the goals and objectives of the mitigative strategies developed and deployed to control and ultimately arrest further spread of the epidemic/pandemic agent.

Collaboration between Clinical and Public Health Laboratories

The process of developing critical pandemic partnerships can be summarized in five steps: (i) timely recognition of a pandemic, usually as a consequence of a managed dialogue between clinical and public health laboratories, primary-care health teams, and infectious disease specialists; (ii) developing a strategic plan with tactical steps; (iii) assigning daily operations to key personnel; (iv) continuous uninterrupted execution of the plan; and (v) continuous plan monitoring and adjustment. Contingency planning serves as a backup if initial plans fail to succeed. Again, such detailed planning requires multiple levels of organization, communication, cooperation, and collaboration. Most epidemics and pandemics are first recognized by laboratory personnel in close coordination with local, state, regional, and national public health epidemiologists and clinicians. Many laboratories across the world abide by their respective mandatory national and global public health reporting requirements and lists of infectious reportable conditions.

On 20 May 2021, the WHO released a significant news item concerning the establishment of an international expert panel with expertise on animal and human health in order to develop a comprehensive understanding of how diseases with the potential to trigger pandemics emerge and spread (69). This panel will operate under the One Health initiative, which acknowledges that human health is closely connected to the health of animals and the world's overall environmental health. It is through an understanding of the linkages between the health of people, animals, and the environment that the world may come to address virtually any threat to animal and human health while at the same time preventing disruption to agri-food systems. Implicit in the One Health initiative is the anticipation that the expert panel tasked to study the emergence of pandemics will operate in a spirit fostering a transdisciplinary, collaborative, transparent, and multisectoral approach with the overarching goal of achieving optimal health outcomes by helping to understand how it might be possible to limit the emergence of future pandemics (69).

Key first steps in the One Health partnership will include systematic analyses of available scientific knowledge about

本书版权归John Wiley & Sons Inc.所有

the factors that lead to transmission of a disease from an animal to human and vice versa. Additionally, development of risk assessment and surveillance frameworks, identification of capacity gaps, and agreement on good practices to prevent and prepare for zoonotic and human outbreaks are essential. Such a panel will consider the impact of human activity on the environment and wildlife habitats. Critical areas will include food production and distribution, urbanization and infrastructure development, international travel and trade, activities that lead to biodiversity loss and climate change, and those that put increased pressure on the natural resource base, all of which can lead to the emergence of zoonotic diseases and hence pandemics. This panel will guide development of a dynamic research agenda, including diagnostic laboratories, to develop evidence-based recommendations for global, regional, national, and local action.

Another factor that should be continuously considered is the consequence of biodiversity loss. Each loss of a plant or animal species undermines nature's ability to provide things like clean water and a stable climate. In 2020, in the midst of the COVID-19 pandemic, the United Nations released a report titled "Preventing the Next Pandemic: Zoonotic Diseases and How to Break the Chain of Transmission" (70). In this report, the authors writing for the agency describe the seven major anthropogenic drivers of zoonotic disease emergence (70). While the effects have been discussed for decades, we are now seeing the real-world impacts, including the emergence of new infectious diseases, with increased frequency.

The 2022 World Economic Forum's annual Global Risks Report reveals that world leaders now rank biodiversity loss as one of the most severe risks facing humanity in the coming decade, alongside climate action failure and extreme weather events (71). With more than half of global gross domestic product coming from industries that rely on nature, such as construction, food production, pharmaceutical discovery, travel, and tourism (72), businesses are also calling for action to protect and restore nature, which is essential for a resilient global economy (73).

Global Surveillance

Laboratories, including those with a clinical, commercial, and/or research focus, will need a strategy for responding to the emergence of novel microorganisms capable of widespread dissemination. These approaches will vary from the development and validation of new diagnostics, prior to the widespread dissemination of reagents and instruments from diagnostic vendors, and the ability to disseminate the data to shared data warehouses. To this end, there will need to be discussions at the highest levels among international, national, regional, and local standard-setting organizations as to what constitutes the best next step. The response in Wuhan, China, in December 2019 and perhaps earlier will require scrutiny, not to cast derision but to recognize the networks of communication and subsequent responses that were present or absent across these networks. Such networks may differ across countries, but an early alert system that will allow a local laboratory to alert a national/international clearinghouse that they have uncovered a novel microorganism with pandemic potential will be paramount. Before COVID-19, there were attempts to create such "dashboards" through offices of pandemic preparedness. We need these offices to function now, at local, regional, national, and international levels. For example, in South Carolina, statewide committees were created to advise governing agencies on the ethics, therapeutics, and communication around pandemic preparedness, suggesting an organizational model for an Office of Pandemic Preparedness. When novel organisms emerge, the specifics of the organism and its tropism can be communicated to these agencies to ensure preparedness to address the level of concern, determine the next analyses, and implement steps to address the threat should it transform into a pandemic.

Economic Costs

The economic costs of pandemics are not trivial. It is estimated that the United States at the outset of 2022 had expended US$11 trillion to 16.3 trillion on response, control, and collateral damage due to the COVID-19 pandemic (https://www.covidmoneytracker.org [accessed 25 April 2022]). Laboratories will need to construct budgets to account for new costs associated with epidemics/pandemics. Such budgets can be generated from the existing laboratory costs of COVID-19 and should be projected into every 5-year plan. Projected costs should include funding for new equipment and technologies, including decisions regarding how much genetic sequencing can be performed in a particular laboratory setting, since both the availability (timeliness) of newly mutated coronavirus genetic sequences and the delay in generating and understanding those mutations have had a momentous impact on the day-to-day operations of clinical and public health microbiology laboratories (74).

Vaccines

Once laboratories determine a pathogen's genetic sequence and develop specific vaccines, including passive immunizations, as we have seen for COVID-19, vaccinations should become the dominant mitigative approach for controlling the new pandemic. Unique therapeutics often take longer to transit the regulatory process before they can contribute as a significant mitigative step.

The first successful transfection of a synthetically produced gene, in the form of its DNA packaged within a liposomal nanoparticle into a cell, was demonstrated in 1989 (75). Delivery of "naked" (or unprotected) and synthetically produced mRNA injected into the muscle of a

本书版权归John Wiley & Sons Inc.所有

mouse was demonstrated a year later (76). This study provided some of the first evidence that *in situ*-transcribed mRNA from three target genes, encoding chloramphenicol acetyltransferase, luciferase, and beta-galactosidase, separately injected into the skeletal muscle of mice could elicit protein products (76). From this initial study, the technology has evolved to a point where mRNA vaccines now represent a new class of vaccines (77). One of the significant advantages of an mRNA platform-based vaccine is that, because of its synthetic nature and sequence, independence vaccines may be developed inexpensively and at a scale appropriate for rapidly moving candidate vaccines into trial evaluations (77).

Vaccine Hesitancy

Proper medical care in the best of times and during a pandemic requires significant information be assembled and processed in order to make proper treatment decisions. This struggle occurs whether one is a physician, parent, or patient. The uneasiness with which the general public embraced the use of FDA EUA, and now approved, vaccines against SARS-CoV-2 is best captured by a statement made almost 300 years ago. Benjamin Franklin included in his autobiography the following (78):

> "*In 1736 I lost one of my sons, a fine boy of four years old, by the smallpox taken in the common way. I long regretted bitterly and still regret that I had not given it to him by inoculation. This I mention for the sake of the parents who omit that operation, on the supposition that they should never forgive themselves if a child died under it; my example showing that the regret may be the same either way, and that, therefore, the safer should be chosen.*"

Franklin's perspective evolved regarding smallpox vaccination, which he ultimately supported.

Today, not only is vaccine hesitancy an issue for ending the SARS-CoV-2 pandemic, but also, as recently as 2014–2015, the United States witnessed an epidemic of measles. The outbreak, which began among mostly unvaccinated visitors to Disneyland, in California, led to more than 125 cases, aroused the attention of public health leaders of our nation, and reacquainted a new generation of providers with the signs and symptoms of this long-forgotten childhood and often deadly viral infection. The main reason measles reached epidemic status then was that some areas of the country had low vaccination rates, leading to distrust in public health with an erosion of herd immunity and culminating in an epidemic of cases. Fast forward to 2022, and we are witnessing similar pushback that unfortunately is being magnified for personal and sometimes political purposes. Indeed, laboratorians, academicians, clinicians, public health professionals, and many previously trusted and reputable sources for acting on behalf of public good have now been vilified, with the result that even their very lives are being threatened.

Best and colleagues call to our attention the need to better understand and to explain the use and logic of medical decision making as developed by Raiffa in the 1960s (79, 80). Using the tragic end of Franklin's son, we can visualize the impact of the decision to inoculate or not to inoculate. Here, the mortality data concerning smallpox deaths in Boston in 1721 are remarkable. Close to 98% of those receiving the inoculation lived, while those who received the inoculation and died represented only 2.1% of the 286 individuals evaluated. However, in the development of their argument as to whether Franklin made the right choice for his son, Best and colleagues suggest that if the likely probability of being infected was less than 14.4% in the community, the best choice was to leave Boston. If the probability of being infected was greater than 14.4%, inoculation was the best choice (80). In 2022, the logic of such decision analysis does not lend itself well to the Twitter and sound-bite messaging culture of our modern era. Rather, the decision tree requires timely data from a common and complete data source that can provide information to government communication experts, who can disseminate the information so that the Franklins of the 21st century will not regret the decision to be inoculated.

Collaboration and Linkage of Laboratories to Incident Commands

Recent experience from the SARS-CoV-2/COVID-19 pandemic of 2020 suggests that once a pandemic has been acknowledged by a common and mutually agreed-on global authority, the world should follow more closely the principles championed by the ICS (Fig. 52.3) (81). Use of an ICS management approach has been successfully deployed during disasters and emergencies across the world for years. Applying such ICS principles can result in the effective mitigation of the crisis as well as management of the responses needed to satisfy the emergent needs while limiting the scope of the incident (81).

For any pandemic plan to be successful, collaborating parties should coordinate their planning and execution of their mitigative steps based on ICS principles. One can speculate whether, if the world had aggressively followed such an ICS approach in the earliest days of the COVID-19 pandemic, through adoption of a comprehensive COVID-19 approach of testing, contact tracing, and isolation of the infected, the globe would have been better able to slow the penetrance of the virus within at-risk populations prior to the development and deployment of vaccines and treatments. The ICS diagram illustrates the complexity of such an endeavor, considering the need for sovereign nations to relinquish control to global incident commanders (Fig. 52.3).

本书版权归John Wiley & Sons Inc.所有

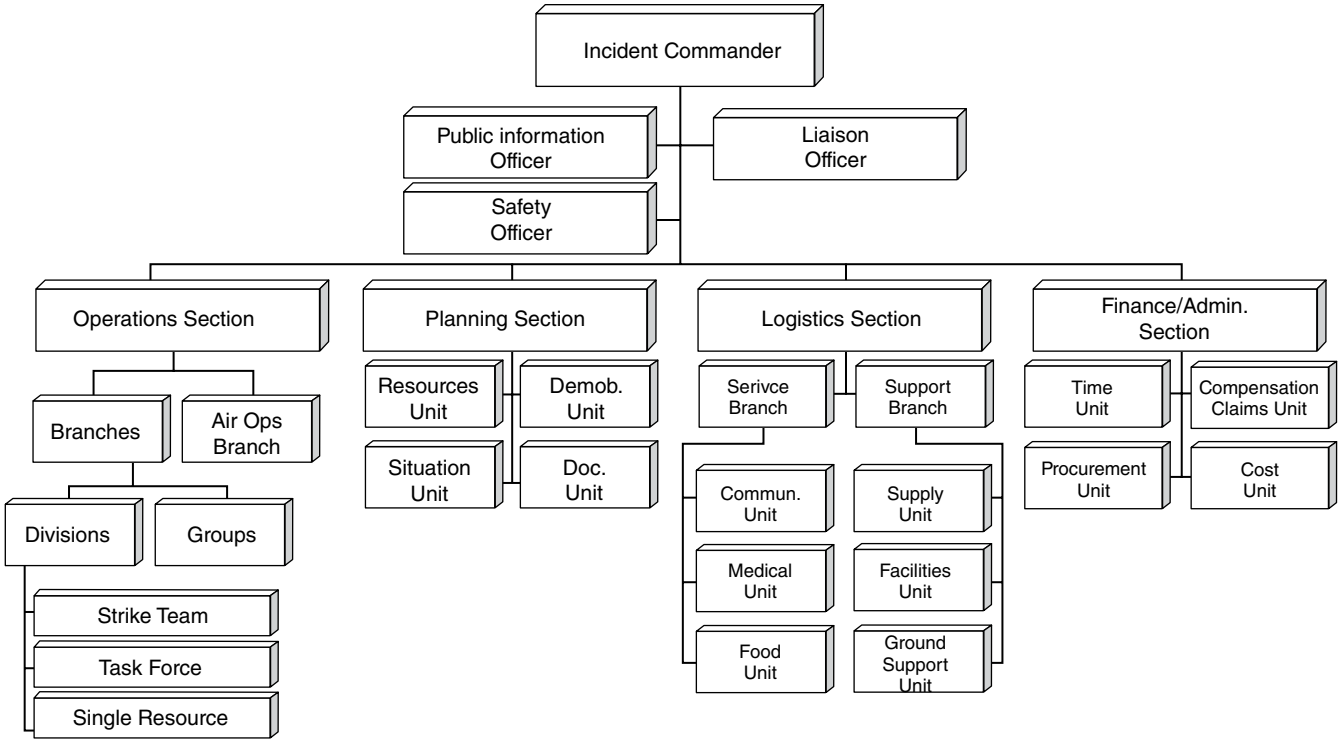


Figure 52.3 Typical organization chart advocated by an ICS approach to disaster management. This illustration presents a generic organization chart of essential offices required for the effective management of any large-scale disaster. Roles for the clinical and public health laboratories may be placed in sections beyond the obvious (medical unit), in that there is a need for laboratory expertise across many of the principal areas of response.

One substantial advantage of employing an ICS approach in controlling a global pandemic is its modular nature. As a pandemic scales up in scope, the need for local mitigative responses will similarly rise. Often, this need is regional, but because of the modular nature of the system, the ICS commanders could quickly and comprehensively delegate functional responsibilities to meet the needs while addressing the overarching goal of limiting further penetrance of the virus into at-risk communities.

In this regard, public health and laboratory professionals assume dominant importance as safety officers, depending on the pathogen and its likely mode of transmission. The incident commanders may be senior public health officials (be it at the local, state, regional, or national level), or they may be military officers or organizations, especially if bioterrorism is suspected, or even knowledgeable politicians or legislatively appointed delegates (Fig. 52.3). The key is communication, collaboration for coordination, and ultimately pandemic control.

The Next Pandemic for Humankind

As the pandemic of COVID-19 continues and eventually abates, humankind faces the next pandemic. Essential to any pandemic response and public health approach are basic common-sense nonpharmacologic preventatives. They include, but are not limited to, widespread testing, identification and isolation of cases, quarantine of close contacts, handwashing, physical distancing, masking of all people (especially indoors and at public events), and disinfection of common-touch surfaces. Other mitigative steps to limit transmission should be incorporated into a comprehensive mitigation plan once it is known how the infectious agent is transmitted.

Medical science has accumulated massive amounts of data concerning many aspects of the COVID-19 pandemic. We have learned much about the molecular pathogenesis of the agent responsible, with much yet to learn. One of the most important facets of this pandemic concerns how we communicated our attempts to limit the spread of this agent through pharmaceutical and nonpharmaceutical interventions.

Never before has the global community faced such a communication barrage with the volume and speed at which new information was released and often misinterpreted. Uncoordinated messaging among nations and a lack of national and global consensus on prevention and control caught the world in a state of future shock. From advances in molecular diagnostics to the development of novel vaccines and pharmacological interventions, the role of the laboratory has been central

本书版权归John Wiley & Sons Inc.所有

to facilitating the ability of public health, not only to be able to track the spread of the pandemic, but also to facilitate effective messaging of the extent to which each of the data elements they contribute may offer opportunities to limit the morbidity and mortality of the pandemic.

We are only beginning to learn of the significant influence that social media platforms may have on public health protection (82). Social media platforms can have both positive and negative influences on public health protections. Al-Dmour and colleagues found that public health awareness and public health behavioral changes acted significantly as partial mediators of the protection of public health (82).

As we prepare for the next pandemic, laboratorians will need to work more closely with social media and communication specialists so that collectively they might offer a better understanding to the public of the role that the laboratory offers and science in general plays in our ability to quickly arrest a pandemic. Specifically, only through an understanding of the significance and limitations of the data being generated by the laboratory can improvements be made to public health awareness, with concomitant behavioral changes.

SUMMARY

Throughout this chapter, we emphasize the importance of the responsibilities and contributions of diagnostic laboratory data to the management of pandemics. We need to remain vigilant so that collaborations between teams of diagnostic laboratories with public health officials, outpatient and inpatient clinicians, academicians, researchers, and others in the community are maintained in a post-COVID-19 world (Fig. 52.4). Absent our collective vigilance, we may not be as fortunate in appreciating the first signals of the next epidemic or pandemic.

Pandemic planning for the future requires each of these diverse teams to respond to a wide array of challenges. Each of these working units must be identified and organized early, especially the key entities. Meetings, both internally and externally, with existing and new partners must begin preemptively, even if officials have not yet declared an official pandemic. From the limited hindsight that we have gained from our experience with the COVID-19 pandemic, we now recognize that it was only through the collaboration of many entities that we were able to limit the morbidity and mortality attributed to catastrophic effects of SARS-CoV-2 on the human race. Future pandemics remain a threat to the very economic, health, and social fabric of society.

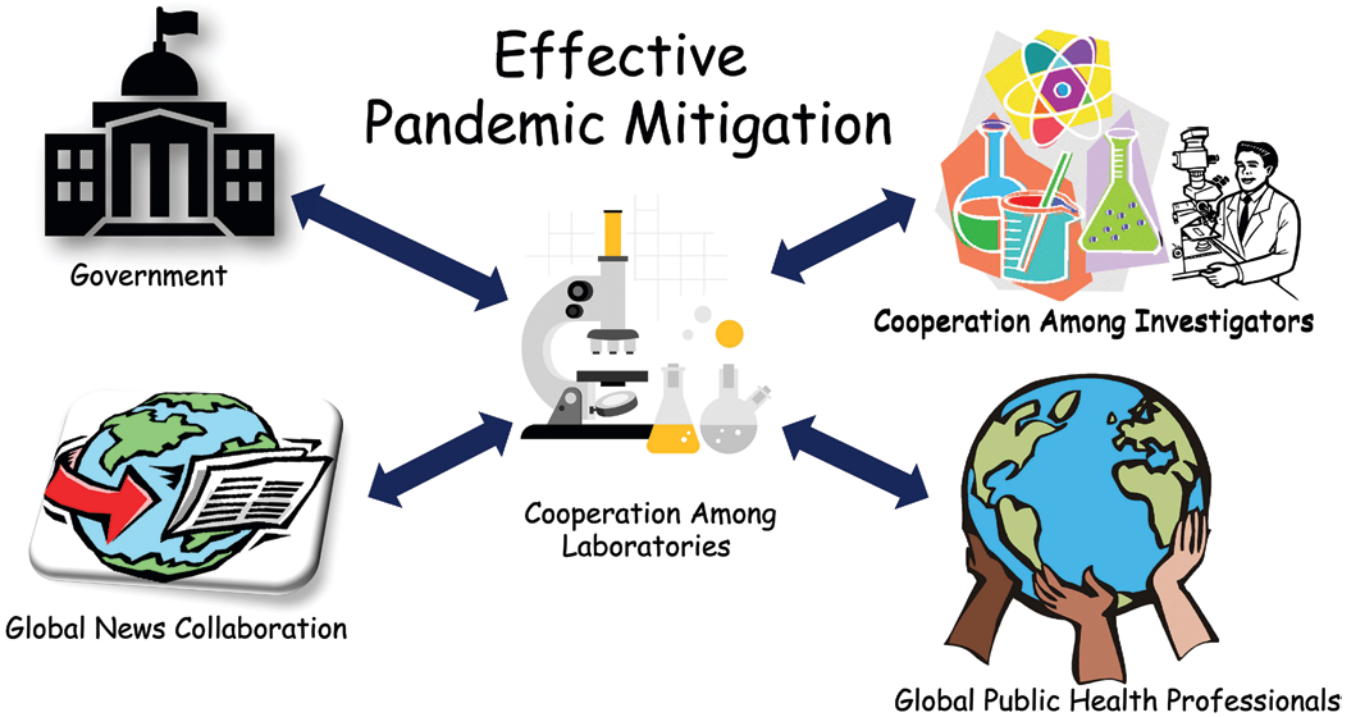


Figure 52.4 Effective pandemic mitigation. Using data generated from advanced diagnostics and insight gleaned from clinical care, the science and healthcare teams need to collaborate with governments and global public health professionals to ensure that release and messaging of relevant information to the public and general news media concerning pandemic control will serve to mitigate and control the spread of the infectious agent.

本书版权归John Wiley & Sons Inc.所有

KEY POINTS

- Laboratories and laboratorians have long been among the first to identify a pandemic pathogen but often among the last to receive proper and timely recognition for their work.
- Only properly equipped and staffed laboratories can accurately identify current and future pandemic pathogens and their unique characteristics.
- Laboratory managers have helped society better understand the importance of robust genomic surveillance efforts to aid public health planning and practice.
- Laboratories cannot properly fulfill their mission without the collaboration of clinicians, academicians, public health personnel, and numerous other healthcare personnel.
- Laboratories are an integral part of increasingly important diverse partnerships necessary to address emerging epidemics and pandemics.
- Global, national, state, and local communication efforts require cooperation and collaboration in addressing the many challenges of pandemics.
- Future pandemics remain a threat to global economic, security, health, and social concerns of all, requiring multifaceted, interdisciplinary informed solutions from all sectors of society.

GLOSSARY

Artificial intelligence (AI) An emerging discipline which combines computer science and robust and often disparate data sets to enable problem-solving and aid in solving complex, multivariable problems.

Basic reproduction number (R_0, pronounced "R naught") An epidemiologic term used to describe the transmission kinetics of an infectious pathogen from one person to another, expressed as the average rate at which an infected person (an index case) will spread the specific infectious pathogen to susceptible persons (also colloquially called the attack rate) under ordinary circumstances.

Big data A term used to denote very large, diverse, and complex data sets, often semistructured, on a given subject, which when used with AI-based methodologies can provide insight into multivariable problems.

Centers for Disease Control and Prevention (CDC) A common term for many nations' primary national public health organization. The most well-known is the United States' Centers for Disease Control and Prevention located in Atlanta, GA.

COVID-19 The official name given to the infectious disease syndrome manifested by SARS-CoV-2.

Data aggregation The process of collecting, processing, and presenting data in a report or summary for a specific objective, such as pandemic planning.

Elimination The term used in public health to indicate that a specific pathogen has been effectively eliminated from a specific geographic region.

Efficacy A term usually referring to a vaccine's ability (efficiency) to prevent substantial disease in a population.

Endemic A term referring to the continued presence of a pathogen in a given geographic area.

Eradication A term denoting the complete elimination of a specific pathogen from the human population.

Epidemic A term referring to a statistically significant rise in the number of cases caused by a specific pathogen.

Emergency use authorization (EUA) A U.S. Food and Drug Administration (FDA) designation to authorize for a limited time the use of a specific laboratory test, medication, or procedure for a specific medical situation.

Extinction The complete global eradication of a pathogen.

Herd immunity A threshold of relative immunity of a given population against a specific pathogen resulting in a generally reduced risk of acquiring significant illness.

Incidence A term used to describe the number of cases from a given illness in a population within (or over) a defined interval of time.

Metagenomics The study of genetic information derived from data generated from nucleic acid analytes collected from defined populations, tissues, or environmental regions that when considered collectively offers insight into the genetic composition of the community or genetic trends being evaluated. Its primary purpose is to improve knowledge of that organism, and in the cases of pandemics, it is to determine genetic sequence variations that may cause phenotypic and clinical differences, especially in areas of viral transmission and pathogenicity.

Microbiome A community of microbes within a defined anatomic location of an animal or environment/niche.

Mode of transmission Method of spread of an infectious pathogen that may be transmitted via direct contact, blood, aerosols, or other environmental exposures.

Morbidity The extent of disease (illness) in a defined population (usually expressed in rates, or numbers per a numerically defined population).

Mortality The number of deaths occurring in a defined population (usually expressed in rates, or numbers per a numerically defined population).

Nowcasting A process of using data aggregation and displaying it graphically to describe a current ongoing situation (e.g., a pandemic) using both real-time observed data and mathematical modeling to compare current and generalizable predicted (or projected) graphics to track changes in the status quo.

Pandemic A condition in which a specific pathogen spreads globally between countries or international borders (usually intercontinental), nowadays usually by air travel.

本书版权归John Wiley & Sons Inc.所有

Pandemic fatigue A term used to describe a psychological state of an individual or community secondary to the persistent spread of a pandemic pathogen.

Polymerase chain reaction (PCR) A specific laboratory technique employing a thermal stable DNA polymerase to geometrically amplify specific genetic sequences using a defined pair of DNA primers yielding a significant concentration of a targeted amplicon.

Prevalence A term used to describe the general amount or number of cases of a given illness or deaths in a population, usually at a given point in time.

Proteomics The large-scale study of proteins (proteomes) and their functions.

Rapid antigen (Ag) testing A testing method where a patient specimen (nasal secretions, urine, blood, semen, etc.) is assessed for the presence or absence of a specific antigen within the analyte to which an antibody conjugate has been raised and embedded; upon successful interaction of the analyte-antibody conjugate, an easily discerned colorimetric or radiometric change denotes the presence of the antigen.

Severe acute respiratory syndrome (SARS) The clinical designation given to the syndrome (constellation of symptoms and signs) of severe pneumonia and numerous other clinical anomalies caused by a coronavirus, first detected in China in 2002, called SARS-CoV-1.

SARS-CoV-1 The coronavirus that caused the pandemic first called SARS in 2002 to 2004.

SARS-CoV-2 A virus in the order *Nidovirales* (genus *Betacoronavirus*, subgenus *Sarbecovirus*). First reported globally by Chinese virologists in late December 2019.

Vaccine efficacy A mathematical calculation describing the efficiency of a vaccine in preventing an infectious disease outcome among vaccinated individuals compared to the same outcomes in a matched unvaccinated group.

Variants of concern (VoC) A designation and operational definition used by the U.S. CDC and WHO for describing mutations occurring within the SARS-CoV-2 virus where there is evidence that the mutated viruses have an increased degree of transmissibility, the ability to cause more severe disease, a significant reduction in neutralization by antibodies generated from previous infection or vaccination, a reduced effectiveness of treatments or vaccines, and/or a higher rate of diagnostic detection failures (83).

Whole-genome sequencing (WGS) A laboratory method employing any number of molecular biological and physical chemical techniques which, in combination with sophisticated software, yields the exact sequence of nucleotides composing the genome of the organism being assessed. The data from WGS offer insight into the genetic relationship between the organism(s) being sequenced and similar organisms or may be used in epidemiology for assessing the relationships of organisms under varying selective pressures in different populations.

REFERENCES

1. **Pasteur L.** 7 December 1854. Lecture given at the University of Lille, Lille, France.

2. **Wolfe N.** 2011. *The Viral Storm: The Dawn of a New Pandemic Age*. Times Books-Henry Holt and Company, LLC, New York, NY.

3. **van Kammen A.** 1999. Beijerinck's contribution to the virus concept—an introduction. *Arch Virol Suppl* **15**:1–8.

4. **Loeffler F.** 1884. Untersuchung uber die Bedeutung der Mikroorganismen fur die Entstehung der Diphtherie. *Mitt Kaiserl Gesundheitsamte* **2**:421–499.

5. **Alexander TS**. 2016. Human immunodeficiency virus diagnostic testing: 30 years of evolution. *Clin Vaccine Immunol* **23**:249–253.

6. **Fauci AS, Lane HC**. 2020. Four decades of HIV/AIDS - much accomplished, much to do. *N Engl J Med* **383**:1–4.

7. **Bansal S, Chowell G, Simonsen L, Vespignani A, Viboud C**. 2016. Big data for infectious disease surveillance and modeling. *J Infect Dis* **214**(Suppl 4):S375–S379.

8. **Chowell G, Cleaton JM, Viboud C**. 2016. Elucidating transmission patterns from internet reports: Ebola and Middle East respiratory syndrome as case studies. *J Infect Dis* **214**(Suppl 4):S421–S426.

9. **Lee EC, Asher JM, Goldlust S, Kraemer JD, Lawson AB, Bansal S**. 2016. Mind the scales: harnessing spatial big data for infectious disease surveillance and inference. *J Infect Dis* **214**(Suppl 4):S409–S413.

10. **Liu S, Poccia S, Candan KS, Chowell G, Sapino ML**. 2016. epiDMS: data management and analytics for decision-making from epidemic spread simulation ensembles. *J Infect Dis* **214**(Suppl 4):S427–S432.

11. **Moran KR, Fairchild G, Generous N, Hickmann K, Osthus D, Priedhorsky R, Hyman J, Del Valle SY**. 2016. Epidemic forecasting is messier than weather forecasting: the role of human behavior and internet data streams in epidemic forecast. *J Infect Dis* **214**(Suppl 4):S404–S408.

12. **Salathé M.** 2016. Digital pharmacovigilance and disease surveillance: combining traditional and big-data systems for better public health. *J Infect Dis* **214**(Suppl 4):S399–S403.

13. **Simonsen L, Gog JR, Olson D, Viboud C**. 2016. Infectious disease surveillance in the big data era: towards faster and locally relevant systems. *J Infect Dis* **214**(Suppl 4):S380–S385.

14. **Wesolowski A, Buckee CO, Engø-Monsen K, Metcalf CJE**. 2016. Connecting mobility to infectious diseases: the promise and limits of mobile phone data. *J Infect Dis* **214**(Suppl 4):S414–S420.

15. **Bbosa N, Kaleebu P, Ssemwanga D**. 2019. HIV subtype diversity worldwide. *Curr Opin HIV AIDS* **14**:153–160.

16. **Hassan AS, Pybus OG, Sanders EJ, Albert J, Esbjörnsson J**. 2017. Defining HIV-1 transmission clusters based on sequence data. *AIDS* **31**:1211–1222.

17. **da Costa VG, Saivish MV, Santos DER, de Lima Silva RF, Moreli ML**. 2020. Comparative epidemiology between the 2009 H1N1 influenza and COVID-19 pandemics. *J Infect Public Health* **13**:1797–1804.

18. **Rabaan AA, Al-Ahmed SH, Haque S, Sah R, Tiwari R, Malik YS, Dhama K, Yatoo MI, Bonilla-Aldana DK, Rodriguez-Morales AJ**. 2020. SARS-CoV-2, SARS-CoV, and MERS-COV: a comparative overview. *Infez Med* **28**:174–184.

本书版权归John Wiley & Sons Inc.所有

19. Soman Pillai V, Krishna G, Valiya Veettil M. 2020. Nipah virus: past outbreaks and future containment. *Viruses* **12**:465.

20. Ferraris P, Yssel H, Missé D. 2019. Zika virus infection: an update. *Microbes Infect* **21**:353–360.

21. Wang MY, Zhao R, Gao LJ, Gao XF, Wang DP, Cao JM. 2020. SARS-CoV-2: structure, biology, and structure-based therapeutics development. *Front Cell Infect Microbiol* **10**:587269.

22. Wrapp D, Wang N, Corbett KS, Goldsmith JA, Hsieh CL, Abiona O, Graham BS, McLellan JS. 2020. Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation. *Science* **367**:1260–1263.

23. Delaune D, Iseni F. 2020. Drug development against smallpox: present and future. *Antimicrob Agents Chemother* **64**:01683–19.

24. Meyer H, Ehmann R, Smith GL. 2020. Smallpox in the post-eradication era. *Viruses* **12**:138.

25. Florescu DF, Keck MA. 2014. Development of CMX001 (brincidofovir) for the treatment of serious diseases or conditions caused by dsDNA viruses. *Expert Rev Anti Infect Ther* **12**:1171–1178.

26. Alvarez-Cardona JJ, Whited LK, Chemaly RF. 2020. Brincidofovir: understanding its unique profile and potential role against adenovirus and other viral infections. *Future Microbiol* **15**:389–400.

27. Frange P, Leruez-Ville M. 2018. Maribavir, brincidofovir and letermovir: efficacy and safety of new antiviral drugs for treating cytomegalovirus infections. *Med Mal Infect* **48**:495–502.

28. Duraffour S, Andrei G, Snoeck R. 2010. Tecovirimat, a p37 envelope protein inhibitor for the treatment of smallpox infection. *IDrugs* **13**:181–191.

29. Russo AT, Grosenbach DW, Chinsangaram J, Honeychurch KM, Long PG, Lovejoy C, Maiti B, Meara I, Hruby DE. 2021. An overview of tecovirimat for smallpox treatment and expanded anti-orthopoxvirus applications. *Expert Rev Anti Infect Ther* **19**:331–344.

30. Alakunle E, Moens U, Nchinda G, Okeke MI. 2020. Monkeypox virus in Nigeria: infection biology, epidemiology, and evolution. *Viruses* **12**:1257.

31. Petersen E, Abubakar I, Ihekweazu C, Heymann D, Ntoumi F, Blumberg L, Asogun D, Mukonka V, Lule SA, Bates M, Honeyborne I, Mfinanga S, Mwaba P, Dar O, Vairo F, Mukhtar M, Kock R, McHugh TD, Ippolito G, Zumla A. 2019. Monkeypox - enhancing public health preparedness for an emerging lethal human zoonotic epidemic threat in the wake of the smallpox post-eradication era. *Int J Infect Dis* **78**:78–84.

32. Vaughn VC, Vaughn HF, Palmer G. 1922. *Epidemiology and Public Health: A Text and Reference Book for Physicians, Medical Students and Health Workers*. C.V. Mosby Company, St. Louis, MO.

33. Iuliano AD, Brunkard JM, Boehmer TK, Peterson E, Adjei S, Binder AM, Cobb S, Graff P, Hidalgo P, Panaggio MJ, Rainey JJ, Rao P, Soetebier K, Wacaster S, Ai C, Gupta V, Molinari NM, Ritchey MD. 2022. Trends in disease severity and health care utilization during the early Omicron variant period compared with previous SARS-CoV-2 high transmission periods - United States, December 2020-January 2022. *MMWR Morb Mortal Wkly Rep* **71**:146–152.

34. Woodcock J. 2021. Addressing new variants: a federal perspective on the COVID-19 response. Senate Committee on Health Education, Labor, and Pensions, U.S. Senate. https://www.help.senate.gov/imo/media/doc/Woodcock7.pdf.

35. Liu Y, Rocklöv J. 2021. The reproductive number of the Delta variant of SARS-CoV-2 is far higher compared to the ancestral SARS-CoV-2 virus. *J Travel Med* **28**:taab124.

36. Worobey M, Watts TD, McKay RA, Suchard MA, Granade T, Teuwen DE, Koblin BA, Heneine W, Lemey P, Jaffe HW. 2016. 1970s and 'Patient 0' HIV-1 genomes illuminate early HIV/AIDS history in North America. *Nature* **539**:98–101.

37. Lorenzo-Redondo R, Ozer EA, Achenbach CJ, D'Aquila RT, Hultquist JF. 2021. Molecular epidemiology in the HIV and SARS-CoV-2 pandemics. *Curr Opin HIV AIDS* **16**:11–24.

38. Food and Drug Administration. 19 May 2021. Antibody testing is not currently recommended to assess immunity after COVID-19 vaccination: FDA safety communication. https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety. Accessed 18 February 2022.

39. Deeks JJ, Dinnes J, Takwoingi Y, Davenport C, Spijker R, Taylor-Phillips S, Adriano A, Beese S, Dretzke J, Ferrante di Ruffano L, Harris IM, Price MJ, Dittrich S, Emperador D, Hooft L, Leeflang MM, Van den Bruel A, Cochrane COVID-19 Diagnostic Test Accuracy Group. 2020. Antibody tests for identification of current and past infection with SARS-CoV-2. *Cochrane Database Syst Rev* **6**:CD013652.

40. Zhang L, Shen FM, Chen F, Lin Z. 2020. Origin and evolution of the 2019 novel coronavirus. *Clin Infect Dis* **71**:882–883.

41. Wang S-F, Lin K. 6 January 2020. Foreign visitors to Taiwan up 7% in 2019. *The China Post*.

42. Wang CJ, Ng CY, Brook RH. 2020. Response to COVID-19 in Taiwan: big data analytics, new technology, and proactive testing. *JAMA* **323**:1341–1342.

43. Dong E, Du H, Gardner L. 2020. An interactive web-based dashboard to track COVID-19 in real time. *Lancet Infect Dis* **20**:533–534.

44. Taiwan Centers for Disease Control. 31 January 2018. NHCC. https://www.cdc.gov.tw/En/Category/MPage/gL7-bARtHyNdrDq882pJ9Q. Accessed 17 January 2022.

45. Bell E, Tappero JW, Ijaz K, Bartee M, Fernandez J, Burris H, Sliter K, Nikkari S, Chungong S, Rodier G, Jafari H, CDC JEE Team, WHO Geneva JEE Secretariat. 2017. Joint external evaluation-development and scale-up of global multisectoral health capacity evaluation process. *Emerg Infect Dis* **23**:S33–S39.

46. Spreco A, Eriksson O, Dahlström Ö, Cowling BJ, Biggerstaff M, Ljunggren G, Jöud A, Istefan E, Timpka T. 2020. Nowcasting (short-term forecasting) of influenza epidemics in local settings, Sweden, 2008-2019. *Emerg Infect Dis* **26**:2669–2677.

47. Alaimo Di Loro P, Divino F, Farcomeni A, Jona Lasinio G, Lovison G, Maruotti A, Mingione M. 2021. Nowcasting COVID-19 incidence indicators during the Italian first outbreak. *Stat Med* **40**:3843–3864.

48. Traeger MS, Wiersma ST, Rosenstein NE, Malecki JM, Shepard CW, Raghunathan PL, Pillai SP, Popovic T, Quinn CP, Meyer RF,

本书版权归John Wiley & Sons Inc.所有

Zaki SR, Kumar S, Bruce SM, Sejvar JJ, Dull PM, Tierney BC, Jones JD, Perkins BA, Florida Investigation Team. 2002. First case of bioterrorism-related inhalational anthrax in the United States, Palm Beach County, Florida, 2001. *Emerg Infect Dis* **8**:1029–1034.

49. Chen L, Zhang G, Liu L, Li Z. 2021. Emerging biosensing technologies for improved diagnostics of COVID-19 and future pandemics. *Talanta* **225**:121986.

50. Islam MM, Koirala D. 2022. Toward a next-generation diagnostic tool: a review on emerging isothermal nucleic acid amplification techniques for the detection of SARS-CoV-2 and other infectious viruses. *Anal Chim Acta* **1209**:339338.

51. Mina MJ, Parker R, Larremore DB. 2020. Rethinking Covid-19 test sensitivity - a strategy for containment. *N Engl J Med* **383**:e120.

52. Vandenberg O, Martiny D, Rochas O, van **Belkum A, Kozlakidis Z**. 2021. Considerations for diagnostic COVID-19 tests. *Nat Rev Microbiol* **19**:171–183.

53. World Health Organization. 2020. WHO lists two COVID-19 tests for emergency use. https://www.who.int/news/item/07-04-2020-who-lists-two-covid-19-tests-for-emergency-use. Accessed 8 February 2022.

54. Sah R, Rodriguez-Morales AJ, Jha R, Chu DKW, Gu H, Peiris M, Bastola A, Lal BK, Ojha HC, Rabaan AA, Zambrano LI, Costello A, Morita K, Pandey BD, Poon LLM. 2020. Complete genome sequence of a 2019 novel coronavirus (SARS-CoV-2) strain isolated in Nepal. *Microbiol Resour Announc* **9**:e00169–20.

55. FDA. 2023. In vitro diagnostics EUAs – molecular diagnostic tests for SARS-CoV-2. https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2. Accessed 5 September 2023.

56. Tsang NNY, So HC, Ng KY, Cowling BJ, Leung GM, Ip DKM. 2021. Diagnostic performance of different sampling approaches for SARS-CoV-2 RT-PCR testing: a systematic review and meta-analysis. *Lancet Infect Dis* **21**:1233–1245.

57. Dyer O. 2021. Covid-19: South Africa's surge in cases deepens alarm over omicron variant. *BMJ* **375**:n3013.

58. Hirabara SM, Serdan TDA, Gorjao R, Masi LN, Pithon-Curi TC, Covas DT, Curi R, Durigon EL. 2022. SARS-COV-2 variants: differences and potential of immune evasion. *Front Cell Infect Microbiol* **11**:781429.

59. YangYang, Gong X, Yang L, Li J, Zhang J, Wei L, Ye G, Tang Y, Jiang Y, Li J, Lin Y, Wang F, Lu H, Liu Y. 2022. Regular and booster vaccination with inactivated vaccines enhance the neutralizing activity against Omicron variant both in the breakthrough infections and vaccinees. *J Infect* **84**:579–613.

60. Bai Y, Du Z, Xu M, Wang L, Wu P, Lau EHY, Cowling BJ, Meyers LA. 2021. International risk of SARS-CoV-2 Omicron variant importations originating in South Africa. *medRxiv* http://dx.doi.org/10.1101/2021.12.07.21267410.

61. Wang C, Liu Z, Chen Z, Huang X, Xu M, He T, Zhang Z. 2020. The establishment of reference sequence for SARS-CoV-2 and variation analysis. *J Med Virol* **92**:667–674.

62. Shu Y, McCauley J. 2017. GISAID: global initiative on sharing all influenza data - from vision to reality. *Euro Surveill* **22**:30494.

63. Mercatelli D, Giorgi FM. 2020. Geographic and genomic distribution of SARS-CoV-2 mutations. *Front Microbiol* **11**:1800.

64. Smyth DS, Trujillo M, Gregory DA, Cheung K, Gao A, Graham M, Guan Y, Guldenpfennig C, Hoxie I, Kannoly S, Kubota N, Lyddon TD, Markman M, Rushford C, San KM, Sompanya G, Spagnolo F, Suarez R, Teixeiro E, Daniels M, Johnson MC, Dennehy JJ. 2022. Tracking cryptic SARS-CoV-2 lineages detected in NYC wastewater. *Nat Commun* **13**:635.

65. Kirby AE, Walters MS, Jennings WC, Fugitt R, LaCross N, Mattioli M, Marsh ZA, Roberts VA, Mercante JW, Yoder J, Hill VR. 2021. Using wastewater surveillance data to support the COVID-19 response - United States, 2020-2021. *MMWR Morb Mortal Wkly Rep* **70**:1242–1244.

66. Randazzo W, Truchado P, Cuevas-Ferrando E, Simón P, Allende A, Sánchez G. 2020. SARS-CoV-2 RNA in wastewater anticipated COVID-19 occurrence in a low prevalence area. *Water Res* **181**:115942.

67. Sangsanont J, Rattanakul S, Kongprajug A, Chyerochana N, Sresung M, Sriporatana N, Wanlapakorn N, Poovorawan Y, Mongkolsuk S, Sirikanchana K. 2022. SARS-CoV-2 RNA surveillance in large to small centralized wastewater treatment plants preceding the third COVID-19 resurgence in Bangkok, Thailand. *Sci Total Environ* **809**:151169.

68. Hotez PJ. 2021. *Preventing the Next Pandemic: Vaccine Diplomacy in a Time of Anti-science*. Johns Hopkins University Press, Baltimore, MD.

69. World Health Organization. 2021. New international expert panel to address the emergence and spread of zoonotic diseases. https://www.who.int/news/item/20-05-2021-new-international-expert-panel-to-address-the-emergence-and-spread-of-zoonotic-diseases. Accessed 12 February 2022.

70. Randolph DG, Refisch J, MacMillan S, Yael Wright C, Bett B, Robinson D, Wernecke B, Lee HS, Karesh WB, Machalaba C, Fraenkel A, Barbieri M. 2020. *Preventing the Next Pandemic: Zoonotic Diseases and How To Break the Chain of Transmission*. United Nations Environment Programme and International Livestock Research Institute Institute, Nairobi, Kenya.

71. Granados Franco F, Kuritzky M, Lukacs R, Zahidi S. 2022. *The Global Risks Report 2022*, 17th ed. World Economic Forum, Cologny, Switzerland

72. Russo A. 2020. Half of world's GDP moderately or highly dependent on nature, says new report. World Economic Forum. https://www.weforum.org/press/2020/01/half-of-world-s-gdp-moderately-or-highly-dependent-on-nature-says-new-report/. Accessed 5 September 2023.

73. IUCN. 2020. More than 560 companies with revenues of US$ 4 trillion call on governments to act now to reverse nature loss. Business for Nature, Geneva, Switzerland. https://www.iucn.org/news/business-and-biodiversity/202009/more-560-companies-back-global-call-action-nature#. Accessed 5 September 2023.

74. Bonotti M, Zech ST. 2021. *Recovering Civility during COVID-19*, p 1–36. Springer Singapore, Singapore.

75. Behr JP, Demeneix B, Loeffler JP, Perez-Mutul J. 1989. Efficient gene transfer into mammalian primary endocrine cells with lipopolyamine-coated DNA. *Proc Natl Acad Sci USA* **86**:6982–6986.

76. Wolff JA, Malone RW, Williams P, Chong W, Acsadi G, Jani A, Felgner PL. 1990. Direct gene transfer into mouse muscle in vivo. *Science* **247**:1465–1468.

本书版权归John Wiley & Sons Inc.所有

77. Hogan MJ, **Pardi N**. 2022. mRNA vaccines in the COVID-19 pandemic and beyond. *Annu Rev Med* **73**:17–39.

78. Franklin B. 1793. *The Private Life of the Late Benjamin Franklin. . . Originally Written by Himself, and Now Translated from the French*. J. Parson, London, United Kingdom.

79. Raiffa H. 1993. Decision analysis: introductory lectures on choices under uncertainty. 1968. *MD Comput* **10**:312–328.

80. Best M, **Katamba A**, **Neuhauser D**. 2007. Making the right decision: Benjamin Franklin's son dies of smallpox in 1736. *Qual Saf Health Care* **16**:478–480.

81. Williams J, **Freeman CL**, **Goldstein S**. 2022. *EMS Incident Command System*. StatPearls, Treasure Island, FL.

82. Al-Dmour H, **Masa'deh R**, **Salman A**, **Abuhashesh M**, **Al-Dmour R**. 2020. Influence of social media platforms on public health protection against the COVID-19 pandemic via the mediating effects of public health awareness and behavioral changes: integrated model. *J Med Internet Res* **22**:e19996.

83. Koelle K, **Martin MA**, **Antia R**, **Lopman B**, **Dean NE**. 2022. The changing epidemiology of SARS-CoV-2. *Science* **375**:1116–1121.

本书版权归John Wiley & Sons Inc.所有

53

Introduction
Lessons Learned from the Laboratory Response to COVID-19
Organization of Healthcare and Laboratory Systems • Implementing New Tests and Surge Capacity • Supply Chains • Appropriate Outbreak Testing • Quality and Staffing • Regulatory Requirements
Framework for Laboratory System Preparedness
Manufacturing and Distribution • Executive Plan • Human Resources Development • Health Informatics • Specimen Logistics and Transportation • mHealth
Laboratory Networks and Biosafety
Future Directions
SUMMARY
KEY POINTS
GLOSSARY
REFERENCES

Laboratory Preparedness

Deirdre Church

OBJECTIVES

To outline the key roles of clinical laboratories in pandemic response

To outline the major issues clinical laboratories must consider in planning for a rapid response to a large outbreak or pandemic, as illustrated by the lessons learned from the recent COVID-19 pandemic

To outline the key components of a framework for laboratory preparedness for an efficient and effective pandemic response

To describe the role of mobile health (mHealth) in pandemic response

To describe the establishment of laboratory response and biosafety networks and their role in enhanced pandemic readiness and response

By failing to PREPARE you are preparing to FAIL.

Benjamin Franklin

Laboratories play an essential role in pandemic response because effective containment of a transmissible pathogen requires prompt access to accurate test results. The various roles played by laboratory systems in patient care and public health response during a pandemic are listed in Table 53.1. Some of the most important roles include the implementation of new tests and urgent scale-up of capacity to meet the emergent demands of high-volume testing of individuals and contacts with suspected infection (1–3). Significant delays in laboratory confirmation of cases can result in secondary delays in outbreak identification, public health response, and provision of clinical care. Public health response to prevent transmission, and resultant morbidity and mortality, heavily relies on access to integrated laboratory data that are disseminated by the fastest means possible. Infection surveillance programs that systematically collect, analyze, and interpret primary health data also rely heavily on laboratory results for the planning, implementation, and evaluation of ongoing infection control and public health practice (3).

The severe acute respiratory syndrome-coronavirus type 2 (SARS-CoV-2; COVID-19 disease) pandemic magnified the global inadequacy of laboratory preparedness, but this problem is not new. Neglect or absence of sustained support for pathology and laboratory medicine has been repeatedly documented in developed as well as resource-limited settings (4–8). Lack of investment for development and support of excellent laboratory systems worldwide has

Clinical Laboratory Management, 3rd Edition
Edited by Lynne S. Garcia.
© 2024 American Society for Microbiology.
doi:10.1128/9781683673941.ch53.

本书版权归John Wiley & Sons Inc.所有

Table 53.1 Role of diagnostic laboratories in patient care and public health response

Provision of appropriate specimen collection device(s)
Order entry: requisitions and electronic
Appropriate logistics for prompt transportation of specimens
Detection of a specific pathogen(s) in a centralized facility
Community-based point-of-care testing (POCT) for rapid pathogen detection near cases/contacts
Communication and sharing results
Discovery of new pathogen(s)
Determining appropriate therapy
Assessing prognosis
Assessing immune response
Disease surveillance
Outbreak response
Pathogen characterization using advanced methods (e.g., proteomics, genotyping by next-generation sequencing)
Pathogen database development and sharing
Development and maintenance of well-characterized biorepositories for specimens and isolates

directly contributed to significant delays in the identification of several recent outbreaks for high-risk pathogens including Ebola and Zika viruses (9–11). During the 2013–2016 Ebola outbreak in West Africa, it took a year to establish required laboratory capacity, resulting in an epidemic that grew to the largest yet recorded, with disease transmission spread into rural Guinea and across international borders (12). Fixed biocontainment laboratories cost US $2 to 3 million to establish and bring into operation and had to be staffed by expatriates with molecular experience in performing manual real-time PCR (qPCR) detection tests for Ebola (13). Additionally, there was a 3-month gap between identification of the index case and the causative agent, which seriously hampered containment efforts, resulting in thousands of excess lives lost and soaring costs attributed to delayed epidemic response (14, 15). Retrospective analyses showed that the disease attack rate could have been reduced from 80% to nil if 60% of Ebola patients had been diagnosed within 1 day instead of 5 days (16). Even though laboratory facilities and point-of-care testing (POCT) in epidemic areas were more widely available during the next Ebola outbreak in the Democratic Republic of the Congo (April 2018), many problems continued to impede laboratory testing, including logistical issues, supply delivery, and chronic shortages of trained and experienced staff (10, 17). The ongoing SARS-CoV-2 pandemic has similarly exposed unresolved serious problems in healthcare and laboratory preparedness, pointing out a chronic global systemic inertia in committing to build and sustain robust outbreak-ready systems.

Why were the world's laboratory systems not initially prepared to mount an urgent COVID-19 laboratory response, despite repeated threats of a potential global pandemic? One of the greatest challenges for pandemic preparedness is the unknown, intermittent, and evolving nature of potential emerging pathogens. Despite local and international surveillance efforts, outbreaks appear unexpectedly in unusual places and may vary from a few local cases to a large regional outbreak or may spread to become a global pandemic. For example, the high costs of continuously preparing for the next "Ebola" outbreak, including continuously stocking specialized personal protective equipment (PPE), validating dedicated testing platforms that may never be used, and maintaining a proficiency and training and quality management program, have been previously reported (8). Because of the dynamic nature of pathogens and outbreaks, healthcare and laboratory systems find it difficult to maintain adequate levels of preparedness. Additionally, the constant pressure on clinical laboratories to reduce costs, while improving outcomes, leads to erosion of pandemic plans whose recommendations are shelved due to competing priorities and thus are not properly resourced for the next event.

This chapter provides an overview of essential components of laboratory preparedness that need to be urgently addressed to rapidly meet the demands of the next large outbreak or global pandemic. While individual laboratory administrators should perform regular strengths, weaknesses, opportunities, and threats (SWOT) analyses of their local system preparedness, national and international programs are urgently needed as well, to address laboratory preparedness on a global scale.

Lessons Learned from the Laboratory Response to COVID-19

Many barriers potentially impede a well-coordinated and sustained laboratory response (Table 53.2). Several reports already highlight lessons learned from the suboptimal laboratory response to the current COVID-19 pandemic in the United States (18–21) and many other high-income countries. This new respiratory virus rapidly overwhelmed sophisticated healthcare and laboratory systems in the world's most resourced countries, despite decades of planning for pandemic influenza (22, 23). While the situation, resources, and challenges varied within and across jurisdictions, significant barriers occurred in implementation of new COVID-19 tests and testing capacity, as well as logistical issues, supply chains, quality and staffing concerns, and regulatory and policy issues (7, 18–21). The U.S. Centers for Disease Control and Prevention (CDC) and other national public health agencies faced problems in developing and rolling out laboratory-developed COVID-19 real-time PCR tests. Immense global competition for supplies, reagents, kits, and instrumentation additionally delayed testing scale-up in many countries, so that

本书版权归John Wiley & Sons Inc.所有

Table 53.2 Impediments to laboratory preparedness for large outbreaks and pandemics

Barriers	Challenges	Potential solutions
Health system/laboratory infrastructure		
Laboratory facilities	Many health systems do not readily have access to modern facilities that meet the physical and operational standards for working with Risk Group 3 and 4 level pathogens.	Preemptively build sufficient higher-containment diagnostic laboratories in strategic locations. Laboratories should be designed to handle pathogens requiring a higher level of containment appropriate for working with Risk Group 3 and 4 level pathogens (e.g., Ebola, SARS-CoV-2, etc.).
Laboratory space	Microbiology laboratories in many jurisdictions are old and inadequately designed to efficiently perform high-volume advanced molecular testing.	Preemptively build modern microbiology laboratories to address current and future anticipated outbreak demands. Laboratories should be designed to handle automated high-volume molecular testing for detection of Risk Group 2 and 3 pathogens.
Instrumentation	Laboratories may not have the required instrumentation to automate high-volume molecular testing.	Ensure that local laboratories have the necessary instruments ready to adapt to high-volume molecular testing. Maintain and enhance existing commercial and generic automation purchased to address the COVID-19 outbreak in all laboratory sectors (i.e., not just public health). Establish capital plan to enhance local/national and global automation capable of performing generic high-volume molecular testing.
Surge capacity	Healthcare systems have consistently decreased laboratory operating budgets to barely meet existing patient care needs. There is no excess capacity to address outbreaks.	Plan for surge capacity within laboratory systems to address outbreaks. Plan for a rapid and flexible scale-up of capacity to allow high-volume outbreak testing (i.e., thousands per day) without compromising existing patient care needs.
System and operational silos	Several types of microbiology laboratories may perform testing in each jurisdiction. Often public health, diagnostic, and private sector laboratories operate within separate silos with little coordination of governance, mandate, or menus.	Break down laboratory system silos for best performance. Streamline the governance, funding, and operations between different types of laboratories to ensure immediate coordinated testing response. Define the roles of individual laboratories in outbreak response including public health, diagnostic hospital, and community-based facilities and the private/commercial sector.
Human resources	Insufficient availability of highly skilled medical/scientific and medical laboratory assistance and technologists	Increase training programs. Develop cross-training programs among employees in molecular methods. Create streamlined HR processes and procedures for redeployment of staff from other disciplines. Develop partnerships with academic institutions to cross-train their technicians, graduate students, etc., to work in a clinical laboratory setting.
Informatics and data management	Healthcare and laboratory systems do not universally have information systems. There is a lack of connectivity between various information technology (IT) systems.	Create connectivity solutions locally, to ensure real-time order entry, analytics, and results reporting among various healthcare sectors (i.e., public health and frontline services). Create connectivity solutions nationally and globally to enable real-time data reporting.
Transportation/logistics	Inadequate and incomplete specimen transportation and logistics capabilities/capacity exists in many jurisdictions. Resource-limited and remote areas with inclement weather have a heightened problem.	Plan and implement detailed local and national transportation/logistics networks. Include novel solutions for resource-limited and remote areas with inclement weather (e.g., low- and middle-income countries, Northern Canada). Consider novel delivery modes such as drones.
Mobile and at-home testing services	Mobile and near-patient laboratory services are critical for vulnerable populations who do not or cannot routinely access healthcare via a centralized laboratory system.	Adopt new models of laboratory testing for routine services to rural, remote, and vulnerable groups. Models may include mobile, near-patient, point-of-care, and at-home testing depending on the diagnostic needs of a particular group(s).

Manufacturing and supply chain implementation		
Supply chain interruptions	Critical shortages of instruments, parts, personal protective equipment (PPE), supplies, reagents, and materials due to border closures and lockdowns	Preselect suppliers and stockpile essential reagents, supplies, and materials. Establish local and national manufacturing lines for critical supplies during outbreaks, especially for PPE and diagnostics production.
Supply chain shortages	Shortages of essential supplies such as PPE, diagnostic collection devices (i.e., swabs), reagents, and materials	Preselect suppliers and stockpile essential reagents, supplies, and materials. Establish local and national manufacturing lines for critical supplies during outbreaks, especially for PPE and diagnostics production.
Commercial resources	Budgets are set years in advance so that limited funds and capacity are available to divert to support outbreaks. There are currently poor commercialization incentives.	Provide market incentives for manufacturers to develop diagnostic tests for WHO list of pandemic pathogens. Provide funding for stockpiling tests for WHO list of pandemic pathogens during non-outbreak periods. Provide funding for manufacture of flexible test formats such as open access molecular test kits that can readily be adapted for detection of various pathogens.
Quality control/ assurance materials	Availability of positive control material for assay QC is initially limited. Panels for verification of assay performance across the detection range of the assay are initially limited.	Provide market incentives for diagnostics manufacturers to provide appropriate QC materials with their assay kits. Provide market incentives for suppliers to readily produce positive QC materials and assay verification panels.
Diagnostic kit scale-up	Diagnostics manufacture requires funding and time which may both be significant barriers to kit scale-up during an outbreak.	Establish and sustain coordinated partnerships to address diagnostics preparedness with government, academia, and industry. Match small start-up companies/academia with major diagnostic and pharmaceutical manufacturers with established capacity to bring tests to market.
Market-driven product distribution	Lack of sufficient product distribution to remote and resource-limited locations	Establish distribution networks within remote locations and resource-limited countries. Establish a global funding mechanism to ensure worldwide access to pandemic diagnostics.
Diagnostics development		
Insufficient funding for diagnostics development	Manufacturers need adequate profit incentives to develop assays for rare or unusual pathogens/diseases.	Establish global coordinating group for funding coordinated diagnostics development for priority pandemic agents. Establish global funds for market incentives targeted towards priority pathogen diagnostics development.
Lack of community and field-based diagnostics	Tests done close to the patient decrease the result turnaround time and enhance disease control efforts.	Establish market incentives to develop robust point-of-care tests including field-based and home-based formats.
Limited collaboration and coordination among key strategic partners	The current system is siloed so that key strategic partners do not coordinate efforts, leading to duplication. Collaboration between different key partners also needs to be enhanced.	Establish local, national, and global coordinating groups for diagnostics development. Use the Tri-Helix model of innovation to strike lasting partnerships among government, academia, and industry (54).
Lack of coordination with laboratories	Limited coordination currently exists among experts in academia/industry and laboratories with pathogen-specific diagnostic expertise.	Expand local, national, and global networks of expert personnel and laboratories to allow more rapid responses during outbreaks and maximize knowledge and protocol sharing. Partner diagnostics and vaccine developers to find novel diagnostic targets.
Limited collaboration among various types of laboratories	Lack of collaboration and coordination among different laboratory sectors	Establish well-coordinated laboratory networks among public health, public and private diagnostics labs, and academic labs. Laboratory networks would share specimens, biorepositories, inventory, and data during outbreaks. Laboratory networks would collaborate wherever possible to perform validations.
Biorepositories	Lack of well-characterized specimen banks	Develop well-characterized and curated local and international specimen banks. Establish a process for access at a minimum cost for clinical and public health laboratories. Charge higher costs for access to researchers.
Validation	Complex process requiring highly skilled personnel that may take 3 to 6 months to complete	Develop coordinated groups within each jurisdiction to perform assay validation.

matching testing supply to demand took months or longer to rectify. Two years into the pandemic, access to COVID-19 testing in many rural and remote communities in the world remained limited or nonexistent, including rapid point-of-care tests. This section briefly discusses some of the major hurdles facing clinical laboratories in being perpetually prepared to respond promptly to outbreaks.

Organization of Healthcare and Laboratory Systems

Lesson: *The spread of a transmissible pathogen such as SARS-CoV-2 cannot be abated without exceptional testing quality, flexibility, and capacity. Defined governance, accountability, and coordination of laboratory sectors are required in advance.*

Chronic lack of investment and allocation of resources to laboratory medicine by policy makers and funders of healthcare systems was responsible, in part, for delayed access to testing worldwide. Laboratories in developed countries had been under extreme duress for the previous several decades due to repeated rounds of restructure to consolidate and privatize services, mostly to achieve short-term cost savings (4, 24). Some of the other universal problems identified by clinical laboratories in well-resourced countries include inadequate infrastructure and facilities to handle specimens that might contain a high-risk pathogen, lack of appropriate equipment or obsolete instrumentation, and a shortage of highly trained laboratorians including assistants, technologists, and medical/scientific staff (8). However, the situation is worse in many remote and resource-limited locations and countries that remain without even rudimentary laboratory infrastructure for routine patient care (4, 6, 25). Clinical microbiology laboratories bore the brunt of responsibility for COVID-19 detection testing but were particularly under-resourced for several reasons. Prior to COVID-19, both public health and diagnostic microbiology operations sustained years of prior budget cuts, restructure, and inconsistent resourcing that led to constant staffing shortages, high turnover, supply chain deficiencies, closures, and lack of capital to modernize equipment with robotics (2, 26). Additionally, these same facilities faced extraordinary challenges in rapidly converting from whole-cell methods (i.e., culture and microscopy) to advanced molecular and proteomics technologies (27, 28), as well as in the continuous validation and implementation of new tests that were required to address the increased analytic complexity of detecting emerging pathogens and new types of antibiotic resistance (27, 29).

A well-coordinated and integrated approach among various laboratory sectors enhances access and timely delivery of outbreak testing during large events such as a pandemic. Although public health and state laboratories are initially responsible for COVID-19 testing in many jurisdictions, the enormous demand for thousands of tests per day required engagement and rapid implementation of high-volume capacity by bringing diagnostic laboratories and even laboratories in academia and other sectors (i.e., environmental, veterinary, defense, etc.) online as part of a regional response network. Due to the previously outlined problems, many different laboratory facilities other than frontline public health laboratories were not able to implement COVID-19 testing until several months after the pandemic was declared. Ideally, a fully accredited or licensed laboratory response network capable of performing diagnostic testing should be established in advance, which would have coordination and joint working procedures to ensure streamlined outbreak specimen handling, testing, and communication strategies (see Laboratory Networks and Biosafety, below).

Implementing New Tests and Surge Capacity

Lesson: *Complex processes for implementing new tests and scaling up high-volume testing capacity take time, but rate-limiting steps can be mitigated by continuous operational pandemic planning and preemptive resource support within healthcare and laboratory systems.*

Introduction of new tests or devices in clinical laboratories requires a robust and complex process that requires careful planning and coordination (7, 30). Table 53.3 outlines some of the steps for implementation and validation for new tests. Clinical laboratories need to validate commercial products before implementation because tests and devices exhibit substantial variation in performance characteristics in different settings due to differences in patient populations, status of a patient's infection (i.e., asymptomatic versus symptomatic), variations in physical laboratory facilities (i.e., electrical and water supplies), differences in expertise, training, and practice between laboratories, and changes or deterioration in instrument components over time (30). Internal validation documents that the test exhibits the same performance characteristics established by the manufacturer, as part of obtaining approval from a regulatory agency such as the Food and Drug Administration (FDA) in the United States (7, 30).

It is estimated to take from 3 to 6 months to validate and implement a new commercially marketed laboratory test, but it may take much longer for laboratory-developed tests (LDTs) due to more thorough validation requirements. Because of the initial unavailability of COVID-19 commercial tests, which had to be newly developed and approved by regulatory agencies, many facilities implemented their own LDTs (31, 32). Validation of COVID-19 tests was also hampered by the lack of an available patient specimen biorepository (i.e., directly collected or prospectively saved spent patient specimens) (32), commercial test panels, and positive controls prior to the commercial production of SARS-CoV-2 armored RNA for qualitative and quantitative use (33).

本书版权归John Wiley & Sons Inc.所有

Table 53.3 Implementation of new outbreak tests[a]

Process	Required infrastructure/resources	Comments
Testing supplies, reagents, and kits	Continuous supply chain for diagnostic test kits and/or supplies and reagents for laboratory-developed tests (LDTs) Rigorous inventory management Defined budget for outbreak testing to meet surge capacity	Outbreak surge capacity may demand use of a combination of commercial and LDTs with different performance profiles. Redundancy is built into the system by using multiple tests from different suppliers. Surge capacity requires immediate sustained access to all testing materials.
Testing automation	Strategic plan for urgent capital acquisition of instruments to meet expected surge capacity Build excess capacity upfront Defined capital budget for instrumentation to meet and exceed surge capacity	Benefits of automation: • Essential to meet test turnaround times required for optimal outcomes • Essential to meeting and exceeding surge capacity • Essential for optimizing human resources to perform high test volume with limited availability of highly trained personnel • Minimizes redeployment of staff • Ensures the laboratory system can continue to meet other service demands
Outbreak requisition	Develop and implement a separate requisition.	A separate outbreak requisition ensures collection of all public health and clinical data and clearly identifies outbreak specimens.
Information technology (IT) support	Develop and implement laboratory information system (LIS) test orders, results entry, and reporting procedures. Develop and implement interfaces from instruments to the LIS.	IT support is essential for streamlined processes throughout the testing cycle. Clinical decision support tools can also be built into order entry to ensure all information is collected and to minimize order entry errors.
Integrated communication and reporting	Integrate test ordering and reporting structures with external stakeholders and other databases. Establish a critical result reporting process and continuously communicate with providers.	Streamlined communication strategies enable all steps in the testing cycle. Real-time reporting processes and medical on-call access for result interpretation and facilitation of additional specimen testing will assist public health and clinical care efforts.
Human resources (HR) plan	Plan for deployment of staff from other lab areas Recruitment of new staff as required Staff training and competency documentation	An HR plan is a critical enabler of an adequate testing response. Hiring and training highly skilled staff is a rate-limiting step for scale-up of testing.
Validation(s)	Validate all aspects of the testing process including IT orders, interfaces, and reporting.	Validations must be completed prior to writing implementation and approval of SOPs.
Standard operating procedures (SOPs)	Write standard operating procedures (SOPs) according to Clinical and Laboratory Standards Institute (CLSI) or other regulatory guidelines that are specific to each healthcare jurisdiction.	SOPs should be in place prior to commencing testing of outbreak specimens. SOPs should include biosafety and QC procedures.
Quality control (QC)/quality assurance (QA) program	Integrate a comprehensive QC/QA program. Establish a Key Performance Indicator (KPI) dashboard(s) for reporting key metrics.	QC/QA measures are required for outbreak testing quality and safety. KPI reporting via online dashboard(s) enables day-to-day assessment of performance.
Education of users	Educate providers about the new test including procedures for collection, ordering, and interpretation of results.	Critical for error prevention and streamlined front-end processes. Also ensures test accuracy by proper specimen collection and handling.
Workload	Establish processes for workload balancing of outbreak testing depending on daily volumes, scale-up, and facilities capacity.	As applicable to the laboratory setting, workload may need to be balanced between different sectors including but not limited to public health and public diagnostic labs.
Downtime procedures	Establish a regional strategic plan for anticipated system failure(s) that impacts testing ability and capacity.	Anticipate and mitigate all possible problems by building system contingency with multiple different tests and testing redundancy (i.e., excess capacity above expected).
Billing	Develop test charge structures as required for billing.	As applicable to the laboratory setting

[a] Adapted from references 7 and 30.

本书版权归John Wiley & Sons Inc.所有

Since most clinical laboratories commit all available resources to patient- or population-based testing, they operate with limited to no testing surge capacity to easily accommodate large outbreaks or pandemic testing. Initially, outbreak support for surge testing must therefore be established by truncating the test menu to divert and dedicate capacity to pandemic testing. This allows the laboratory system to build surge capacity for outbreak testing above what is required for service, followed by gradually phasing in routine laboratory services, back to full capacity. Even larger, well-resourced laboratory systems, however, struggled during COVID-19 to readily bring enough outbreak testing capacity online without compromising routine services because the demand for thousands of additional real-time PCR tests per day far surpassed anything that had ever occurred or been planned for. COVID-19 pandemic testing therefore continued to divert and deplete the ability of laboratory systems in some jurisdictions to provide routine service, potentially compromising the overall health of their patients and the population. Ideally, enough testing surge capacity would be available to handle the demands of pandemic laboratory support while continuing its core functions.

Supply Chains

Lesson: *Industry, in partnership with international agencies, governments, and healthcare and laboratory systems, must be prepared to rapidly support local and international supply chains for required products at the onset of an outbreak as well as to scale-up rapidly to meet testing demands.*

Diagnostic manufacturing and distribution capacity must be established before an emergent outbreak event for laboratory systems to achieve a timely ramp-up to the required extraordinary testing capacity. During the recent Ebola outbreaks in Africa, diagnostic biotechnology companies and suppliers of commercial test kits, reagents, supplies, and instrumentation had limited initial capacity to dedicate to testing efforts (10). Similarly, supply chain issues plagued COVID-19 testing capacity globally, because of the unprecedented worldwide testing demand that simultaneously occurred (32). Critical shortages occurred globally in access to a wide range of products needed to perform COVID-19 RT-PCR tests including collection devices/media, buffers, magnetic beads, pipette tips, Taq polymerase, commercial test kits, and automated instrumentation. In many countries, manufacturing and distribution of commercial test kits, supplies, and their respective platforms delayed access to high-volume COVID-19 testing for a sustained period (i.e., months to years). Large diagnostic suppliers were also forced by governments to prioritize their own national COVID-19 testing needs before rationing resources to other countries, which heightened global inequities in access to tests. Clinical laboratories had to rely on a combination of molecular LDTs and commercial tests to meet exceptional sustained testing demands that had different SARS-CoV-2 gene target(s), performance profiles, and cycle time thresholds for positive results. Since performance varied across tests, this led to confusion about test interpretations, a high volume of repeat tests using different combinations of tests, and clinical confusion about "indeterminate" results (32).

Appropriate Outbreak Testing

Lesson: *Outbreak testing should be based on public health case definitions for individuals suspected of having symptomatic infection or persons documented to be a close contact of a confirmed case. Widespread testing of the "worried well" who are asymptomatic, or those with no exposure or contact with the outbreak pathogen, potentially leads to delayed test turnaround times and threatens to deplete limited supplies of critical resources.*

COVID-19 testing at the peak of subsequent diseases waves was exemplified by long lines of cars with people waiting for qPCR testing, many of whom were among the "worried well" with limited pre-test probability of having infection. Due to the availability of government-provided COVID-19 testing, individuals in some jurisdictions were encouraged to be tested for COVID-19 repeatedly even though they were asymptomatic and had no realistic exposure to the virus. Although laboratory testing is vital to a well-coordinated outbreak response, appropriate utilization of testing must also prevail even during outbreaks, not only to provide accurate epidemiological surveillance data, but also to prevent false-positive results from testing low-prevalence populations by using a highly sensitive qPCR test and to control inappropriate depletion of limited supplies of critical resources.

Quality and Staffing

Lesson: *Outbreak testing should be performed to the same quality standards published and used for performing all other clinical diagnostic testing. Core components for the maintenance of quality include but are not limited to the accreditation or licensing of laboratories, the presence of a robust quality control program with ongoing monitoring of test performance, and the sustained availability of highly skilled staff.*

Pandemic testing should be performed with the same quality standards required for all other diagnostic testing. First and foremost, highly complex tests should be performed in laboratories that have been accredited and licensed by a recognized agency, and in the United States, COVID-19 testing laboratories have to be licensed under the federal Clinical Laboratory Improvement Amendments (CLIA) regulation (26). This helps maintain an acceptable quality standard of laboratory practice. In some jurisdictions, however, unlicensed and unregulated private

本书版权归John Wiley & Sons Inc.所有

laboratories flourished in providing user-pay service for some or part of the testing process (i.e., specimen collection and transport and/or testing and reporting), particularly to address the demand for COVID-19 screening for travel and workplace safety. The overall quality and reliability of results being reported by these entities cannot be assured without review of their quality control (QC) of the entire testing process against published accreditation standards and manufacturer's requirements.

Testing quality is also highly dependent on a workforce of highly skilled staff with experience, particularly in advanced molecular methods. Critical staffing shortages throughout COVID-19 impeded routine and outbreak testing worldwide (18). Universally, laboratory staff worked extended hours and multiple shifts per day, often 7 days a week, to accommodate COVID-19 testing demand (18). This increased the risk of testing errors and burnout of essential personnel who remained stressed, tired, and overworked. Staff absentee rates climbed due to illness, short-term leaves, and employees retiring or quitting their jobs. Although staff were deployed from other laboratory disciplines with less-essential workloads or nonclinical laboratories (i.e., academic research technicians and graduate students) to perform COVID-19 testing, it takes enormous additional resources and time to hire, orient, and train new staff before performing clinical testing. Proliferation of unaccredited private user-pay laboratories in some locations also competitively hired essential staff away from the core public health and clinical microbiology laboratories performing COVID-19 testing.

Regulatory Requirements

Lesson: *Regulatory approval processes for emergency use authorization (EUA) of products required for outbreak response to known or unknown pathogens need to be seamless among various regulatory agencies to aid in the streamlining of approval processes.*

Diagnostic tests must receive regulatory approval prior to routine clinical use, to provide some measure of their accuracy and safety. Cumbersome bureaucratic regulatory processes, with excess documentation and steps, may impede the approval of new tests and products during an emergent outbreak. The U.S. FDA and similar agencies worldwide faced unprecedented demands for accelerated approval of a plethora of diagnostics, medical devices, therapeutics, and vaccines to combat the COVID-19 pandemic, all within an urgent timeline (34). EUA approval for rapidly developed COVID-19 tests, whether molecular tests, serology, or point-of-care formats, was inordinately slow, resulting in further delays in commercial test kits becoming available (32). Normally the EUA process is rarely used, as it requires each test to be independently evaluated to ensure its adherence to uniform quality and performance standards prior to regulatory approval. However, the COVID-19 pandemic forced important modifications to the FDA's regulatory clearance policies to accelerate testing capabilities and capacity (35). With experience, the FDA improved and clarified the EUA submission process and other procedures during COVID-19 to accelerate the availability of hundreds of new products. As of early 2022, the FDA has granted more than 250 EUAs for SARS-CoV-2 tests, including real-time PCR tests, antibody-based or serological tests, point-of care tests, and rapid antigen tests (36). Additionally, the lack of coordination and overlapping oversight and regulatory responsibilities in the United States among various federal agencies (i.e., CDC, FDA, College of American Pathologists [CAP]) with regard to laboratory test development, approval, and ongoing evaluation also hampered COVID-19 scale-up (32, 36). Once a test receives FDA authorization, however, there is no regulatory program to verify a test's clinical performance, leaving the onus on each laboratory to develop a process for this important quality measure (7).

Framework for Laboratory System Preparedness

A framework for laboratory system preparedness has been proposed and recently reported by Perkins and colleagues, as shown in Fig. 53.1 (10). Key pillars of a comprehensive preparedness strategy include but are not limited to the following: (i) outbreak identification, (ii) diagnostics development, (iii) manufacturing and distribution, and (iv) implementation. Global investment for development and coordination of complex laboratory systems must be in place prior to an outbreak to immediately assist and support local and international management efforts. Access to robotics automation for high-volume testing and access to information technology (IT) to streamline specimen/order data entry, results reporting, and data sharing facilitate the entire process of testing and communication. Ready access to essential specimens, controls, test supplies, and well-developed protocols for outbreak test validations would also minimize testing delays. Advanced coordination of distribution, logistics, and supply chain partners within an outbreak region's laboratory system assist with the rapid scale-up of testing capacity. The administration and operations of the critical enablers of outbreak response, as outlined in this section, may be neglected but underpin all laboratory preparedness efforts.

Manufacturing and Distribution

A global strategic plan for manufacturing and distribution would ensure ready availability of initial and ongoing supply chains for pandemic response. A global commercial diagnostic supplier consortium would preemptively lock in plans for immediate and ongoing outbreak testing

本书版权归John Wiley & Sons Inc.所有

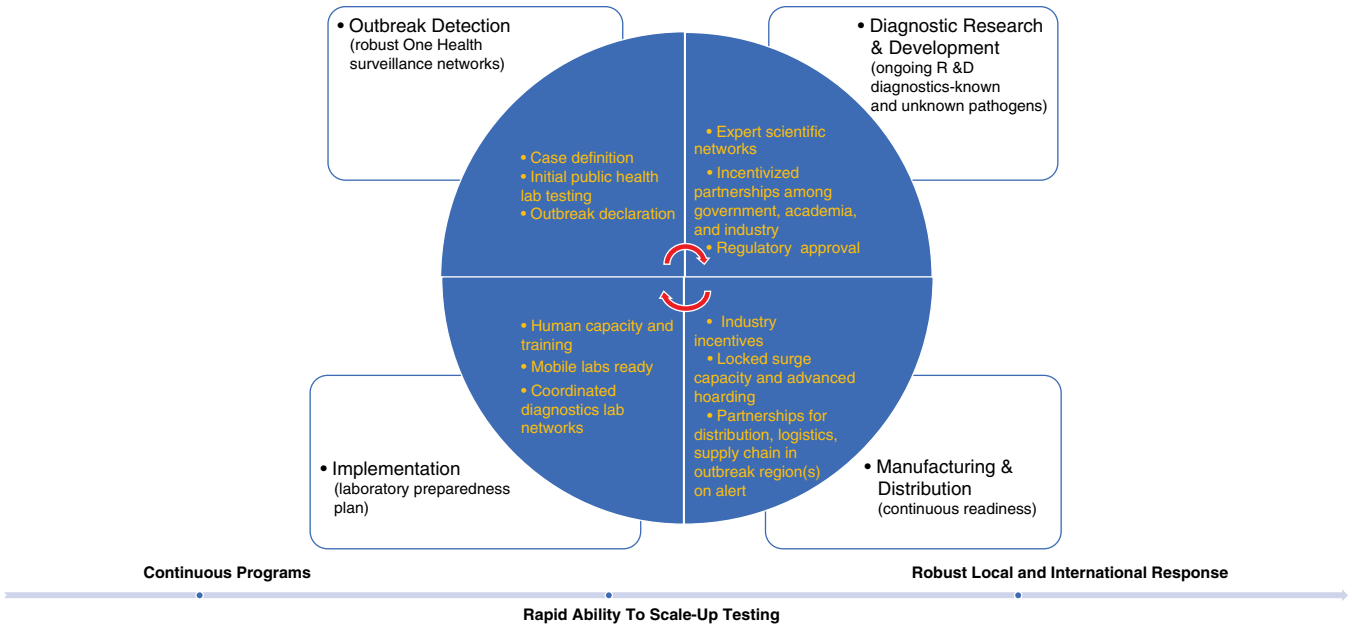


Figure 53.1 Framework for diagnostic preparedness for known and unknown outbreaks (modified from reference 10).

support on a regional, national, or global scope. Diagnostic tests for detection of all World Health Organization (WHO) priority viral pathogens with pandemic potential should be immediately developed and validated, followed by advanced manufacture and stockpiling of all necessary test components including instrumentation, reagents, supplies, and commercial kits. Industry incentives would ensure logistical readiness for outbreak pathogen testing even though other products may be more profitable to manufacture competitively (10). Locally, purchasing, distribution, logistics, and supply chain partners and capabilities would be placed on alert at the first indication of a large outbreak or pandemic. Region-specific laboratory planning should estimate the initial and scaled-up demand for immediate and ongoing testing capacity and capabilities throughout a prolonged outbreak. As shown by COVID-19, it would be prudent to overestimate regional and global testing demand and build in testing redundancies and contingencies to mitigate unanticipated supply chain issues for pandemic testing, so as not to face prolonged periods of downtime or limited ability to provide tests.

Executive Plan

Local executive and management support is crucial for laboratory preparedness and mounting a robust pandemic response. A local or regional leadership team (i.e., Laboratory Executive and Assistance Team or LEAT) responsible for the governance, accountability, and coordination of all laboratory sectors and services should be enacted at outbreak onset. Within this volume, section IV (Requirements for Effective Laboratory Management) and section V (Financial Management) provide details of executive management of laboratory operations, and readers should consult these important chapters when developing an executive strategic plan, which should include but not be limited to the following:

- Governance of Laboratory Executive and Assistance Team (LEAT)
- Accountability of decision making within the laboratory system
- Accountability of decision making within the healthcare system
- Coordination of laboratory response across different regional sectors (i.e., public health; private and public health diagnostic, commercial, academic laboratories)
- Funding and finance plan
- Inventory plan for required laboratory supplies and reagents including personal protective equipment
- A capital equipment plan that includes maintenance schedules, depreciation, and purchase of instruments required for surge testing capacity
- Preemptive purchasing supplier agreements for supplies, reagents, and equipment required to meet a testing surge
- Review of laboratory biosafety readiness, including stockpiling personal protective equipment, staff fit testing for N95 use as required by pathogen risk level, and facilities review to meet biosafety requirements by pathogen risk level

本书版权归John Wiley & Sons Inc.所有

The executive plan should be regularly reviewed and updated at a minimum of every 6 to 12 months. The plan should be immediately revised at the first alert of a potential large outbreak or pandemic to determine laboratory system readiness through a SWOT analysis. Purchase orders for all projected additional supplies, reagents, and instruments to meet estimated testing surge capacity should be urgently approved to ensure product availability and prompt delivery. Standing orders for required supplies and reagents should be put in place to secure and ensure continuous product delivery to meet current and future testing demands during scale-up.

Human Resources Development

Worldwide there is a ubiquitous need for rigorous diagnostics training due to human resource limitations, particularly in advanced technologies. A global plan with adequate funding and resources is urgently needed to ensure the ongoing availability of highly qualified laboratory personnel. Developed countries have identified critical staff shortages as a pressing issue impacting their ability to operate routine services, and this situation is eminently worse in remote and resource-limited areas as well as low- and mid-income countries. Laboratories currently have difficulty hiring highly skilled staff even without the extra demands brought by a pandemic. Finding qualified data entry staff, medical assistants and technologists, and medical scientific personnel with expertise and experience in clinical microbiology molecular training substantially heightened staffing issues for many laboratories during COVID-19.

Global health diagnostics support must include robust and sustained plans to ensure there are enough highly qualified laboratory personnel to oversee and perform testing for routine clinical care in addition to outbreak surge capacity. Available highly skilled personnel from all sectors (public health, clinical, commercial, and academic) and other areas of the laboratory (i.e., pathology, hematology, cytogenetics, etc.) should be actively recruited into cross-training programs so that they could be rapidly redeployed into public health and clinical microbiology operations to assist with outbreak testing surges, as occurred during COVID-19. Rigorous training programs should instruct participants in both required analytical methods and biosafety operational requirements, including the donning and doffing of PPE. Regular competency assessments and retraining should continue for cross-trained staff to ensure laboratory readiness. Local union representatives should assist with development of preemptive staff agreements to ensure efficient and effective redeployment of staffing across laboratory areas and sectors, and to enable ready balancing of testing workloads between public health, diagnostic, and other laboratories within a jurisdiction. A staffing dashboard should be implemented to monitor the staffing requirements, because increased absenteeism due to stress, mental health, and illness can be anticipated during a prolonged outbreak. Planned days off and vacations for staff should proceed to prevent staff burnout as much as possible.

Health Informatics

The COVID-19 pandemic demonstrated the pivotal role that IT plays in managing the pandemic response. A robust clinical informatics team must be deployed early and dedicated to enabling regional clinical information systems for public health response and patient care. Several key capabilities should be in place as follows:

- Rapid deployment
- Information exchange
- Rapid response for electronic medical records during emergencies
- Emerging internet-based technologies
- Data dashboards
- Privacy protection

Clinical information systems should be in place for not only routine but emergent patient care during a pandemic (37, 38). Admission, discharge, and transfer (ADT) systems bilaterally interfaced to laboratory information systems (LISs) enable support for hospitalized patient care. The connection to an electronic health record (EHR) also allows rapid exchange of information such as patient referrals and test results among medical facilities, public health, and providers, provided the existing IT systems are rapidly configured to specifically respond during outbreaks. Specific ADT and test orders should be preconfigured that could be readily adapted to new pathogens/threats, and a standardized EHR process should also be developed to quickly respond to public health emergencies. Consideration should be given to adapting IT systems for screening and triage processes, streamlined patient care, and test orders that enable downstream order entry for laboratory and pharmacy systems and outbreak-related information statistics. Data dashboards were used extensively in the COVID-19 pandemic, collating real-time public-health data, including confirmed cases, deaths, and testing capacity, to keep the public informed and support policy makers in refining interventions. However, for dashboards to be effective tools, the quality and consistency of data collection remain challenging. In addition, lack of international standards for reported statistics makes comparisons between in-country jurisdictions and global locations difficult.

Digital technologies can supplement clinical and laboratory notification, using symptom-based case identification and widespread access to community testing and self-testing and with automation and acceleration of

本书版权归John Wiley & Sons Inc.所有

reporting to public-health databases. In some jurisdictions, a variety of emerging technologies were also used during the COVID-19 pandemic to assist with information delivery, case detection, screening, online services, risk assessment, and intelligent diagnosis. Cloud computing, big data, mobile internet, artificial intelligence, and 5G mobile networks were used to enable prevention and control measures. For example, tricolored health QR codes were used in China for individual tracking; these played an important role in case prevention and control as well as accelerating the economy by allowing people to return to work (38). Health QR codes combined with big data technology can readily identify direct and indirect contacts of confirmed and suspected patients with COVID-19 and allow public health to promptly locate potentially infected people to institute prevention measures.

Privacy protection of healthcare data, however, is a paramount concern for data connectivity to healthcare IT systems, particularly for nonsecured mobile devices (see "mHealth" below). Substantial development and stakeholder coordination between the hardware and software components in an mHealth system must also be in place to improve mHealth device connectivity with the rest of the healthcare system IT network. Historically, clinical data, including laboratory results, have been stored in information systems that are secure, but mHealth device data may not be securely stored or may easily be shared across multiple applications or connected to a jurisdiction's electronic health record (27, 39). Both contextual and ethical challenges, including a lack of standardized data security to ensure privacy, must be solved to bring about the data-sharing capabilities required for mHealth devices and programs (40). International governance and regulation standards are being developed in the European Union as part of a General Data Protection Regulation to address these problems, but users must also be educated to consent to all aspects of how their data will be used within a mobile network.

Specimen Logistics and Transportation

The front-end processes of laboratory testing, from specimen collection to test ordering, individual data entry and receipt, and specimen accession, are critical processes that must be worked out to implement any new test. The potential benefits of procuring and stockpiling available collection devices for anticipated outbreak testing cannot be overemphasized. Initial and ongoing COVID-19 testing depleted the global supply of appropriate swabs that could be used for collection of many nasopharyngeal or throat/nasal specimens. Since transmissible human infections are acquired through only a few routes—e.g., respiratory, ingestion, blood-borne, sexual contact—and there are well-established specimen collection methods depending on the site/source of infection, stockpiling of collection devices to meet the anticipated initial demand for regional testing seems prudent.

Laboratories also need to rapidly establish additional specific transportation routes to not only deliver and continuously resupply outbreak assessment testing centers/locations with collection devices but also to regularly collect patient specimens. All outbreak specimens must be given priority transportation to the nearest available testing laboratory to decrease the time to result as much as possible. Testing laboratories also need to be performing outbreak testing continually up to 24 hours/7 days per week to provide timely results. A logistics team should continuously monitor and document front-end performance against expected targets for collection-to-receipt timing of specimens by the laboratory.

Test ordering and result reporting should also be computerized. The potential benefits of computerized provider/collector order entry (CPOE) in laboratory medicine, compared to reliance on totally manual front-end processes, have been documented (41). Although <5% of hospitals in many developed nations such as the United States remain without computerized order entry systems, implementation of CPOE should be prioritized regardless of facility size or complexity (18). Access to CPOE can improve outbreak management and patient care, as CPOE can provide standardized orders, minimize handwritten information errors, eliminate use of ambiguous abbreviations, facilitate resolution of discrepant or redundant orders, and improve the ability of laboratories to report critical values electronically. Use of CPOE systems also substantially improves the timeliness of result reporting to an EHR and the quality of audits and occurrences reviews (41).

mHealth

Traditional laboratory systems worldwide must develop and engage the public in mobile health (mHealth) services. mHealth is defined by the WHO as medical and public health practice supported by mobile devices, and mHealth has been used to address challenges in health systems, health education, and surveillance (10, 39, 40, 42). mHealth will not only shift diagnostic and surveillance control of infectious diseases away from centralized laboratory facilities but will also empower patients to take charge of their own health. Robust mobile laboratory services will improve access to patients regardless of sustained resources, so that traditional laboratories can retain control over widespread community-based diagnostic infectious-diseases testing for a rapidly increasing menu of tests. Establishment of robust mobile health services for routine patient care and public health testing will also greatly enable pandemic response once the appropriate testing formats for a new pathogen are available.

本书版权归John Wiley & Sons Inc.所有

Most people worldwide do not have access to facility-based diagnostic testing, making this a major challenge for patient care and public health. Remote and vulnerable populations often do not seek care in centralized clinics, particularly in urban areas, because for certain infectious diseases (i.e., HIV infection) there is stigma attached to the illness as well as competing demands and transportation problems (43). Recent systemic review found that mobile testing outside clinics increased diagnostic test access compared with conventional testing (40). Further, the risk of adverse events associated with mobile laboratory service is minimal, and patients prefer self-sampling. Improvements in diagnostic technology and convergence with mobile devices will increasingly allow infectious diseases testing to occur through self-testing, self-sampling, and institutional testing near the patient and outside traditional clinical settings (42).

In many low- and middle-income countries, implementation of POCT has begun to close major gaps in laboratory service. Previously, self-sampling for sexually transmitted infections and HIV testing led the way in mobile health laboratory service, providing increased diagnostic test uptake without disturbing linkages to care (43, 44). However, the recent COVID-19 pandemic accelerated the deployment of mobile testing services that use rapid tests because lockdown situations restricted movement and access to healthcare services for patients, and for prolonged periods of time diagnostic testing became limited to urgent medical situations (45–47). mHealth provides testing outside traditional healthcare and laboratory systems, which provides greater flexibility for people to develop different service delivery models and access services, regardless of location.

Rapid advances in portable communications technologies and digital computing have also improved the speed and efficiency with which data can be processed and exchanged (48). However, it is important for digital self-testing services to incorporate linkages to care service such as real-time online supervised testing, digital tracking of test kit utilization, and availability of follow-up calls or other interventions (40). Most mHealth services have focused on the use of established mobile technologies, such as text messages and calls, to connect healthcare workers and patients to each other and to test results (48). The COVID-19 pandemic also spurred healthcare and laboratory systems worldwide to implement and enhance mobile testing services for patient specimen collection and rapid diagnostic testing using multiple test formats (40). Mobile vans were sent into many community locations to improve COVID-19 testing access for remote and vulnerable populations. Streamlining the process, however, requires connection of portable diagnostic devices that automatically report results (Fig. 53.2). Connected POC diagnostic technologies and wearable devices use various types of sensors (i.e., biochemical, electrochemical, etc.) already built into the smartphone or externally that use the device's computing and connection capabilities to create a connected diagnostic (42). Ideally, these devices would be developed alongside the WHO ASSURED criteria (Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free, Delivered) that define the ideal POC diagnostic and key design principles (32, 40).

Despite the enormous potential of an mHealth intervention using portable connected diagnostic devices, processes need to be developed to link these directly to infectious diseases clinical care pathways and surveillance programs (40, 42). This requires secure information

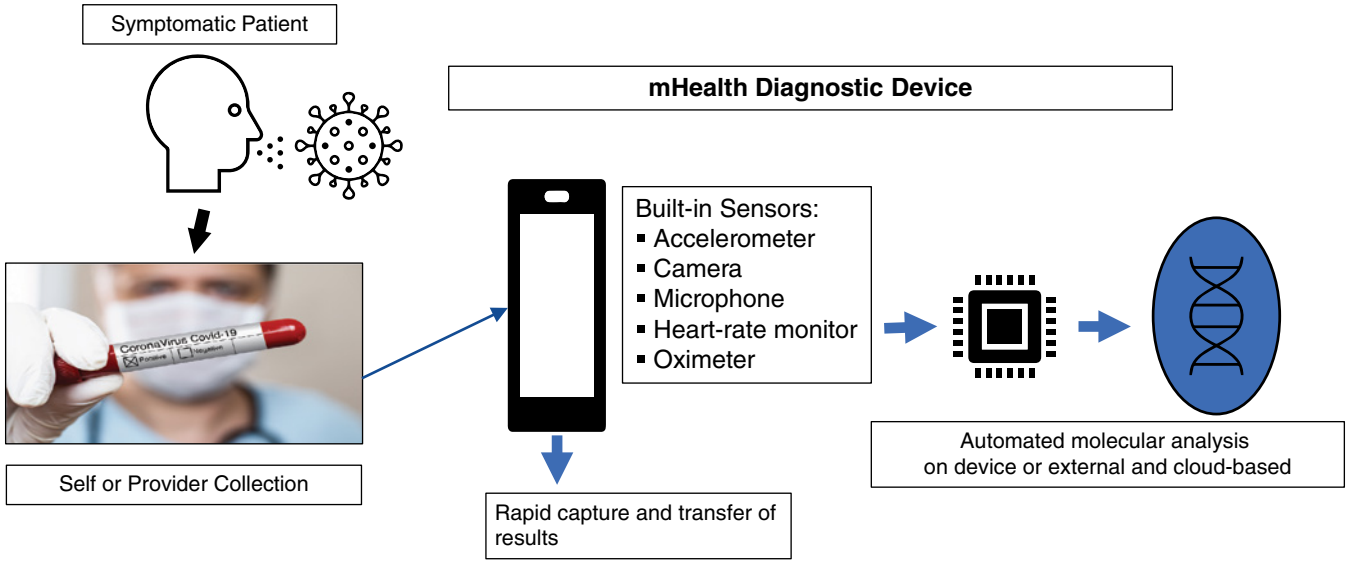


Figure 53.2 Connected diagnostics on a mobile smartphone device.

本书版权归John Wiley & Sons Inc.所有

systems to be in place for secure data transfer, analysis either at source or remotely, and data storage. Linkages to specific clinical care pathways may be a challenge in many jurisdictions, but laboratory information is only useful if it is promptly reported to and acted upon by either the patient, the healthcare professional, or a clinic within well-developed clinical care pathways. Optimally deployed, mobile connected devices should be part of the arsenal used within laboratory networks with established linkages to well-developed healthcare systems.

Laboratory Networks and Biosafety

Regional laboratory systems are exceedingly complex, with overlapping menus and mandates. A mixture of public health or state laboratories service population-health needs, while diagnostic laboratories perform testing for individual patient care. Generally, public health laboratories are funded by governments, but within the diagnostic sector, a mixture of public and private funding models occur. This leads to a siloed approach to administration within the various laboratory sectors, often with little coordination of efforts both routinely and during pandemics. Although diagnostic, surveillance, and pathogen genotyping services may initially be provided exclusively by public health laboratories, the demands for testing and the need for a timely test result mean that testing capacity must be expanded and distributed across the entire laboratory system, locally and nationally. COVID-19 again demonstrated the overall lack of preparedness even in many developed locations, with poor initial integration and coordination across laboratory sectors in meeting testing demands.

To better coordinate laboratory sector activities, many nations have been building laboratory response networks. Ultimately nations should aim towards building a robust national laboratory system that coordinates all stakeholders' responses to a pandemic or other disaster event. In 1999, the United States envisioned building such a system by linking diagnostic private-sector and clinical laboratories with public health, veterinary, food safety, and environmental testing laboratories to create seamless systems within each state to enhance public health surveillance, emergency response, laboratory support, and quality improvement (49). To this end, the framework for a national Laboratory Response Network (LRN) was established as a partnership between the CDC, the American Public Health Laboratories, and the Federal Bureau of Investigation (50). The initial framework was used to respond to bioterrorism threats and included three organizational tiers: (i) Tier 1, federal government laboratories including the CDC and laboratories within the U.S. military system; (ii) Tier 2, state public health laboratories and other governmental laboratories with advanced skills that qualify them to be reference laboratories capable of agent isolation and diagnostic testing using molecular protocols; and (iii) Tier 3, more than 25,000 private and commercial diagnostic laboratories nationwide that serve as sentinels in the system. Figure 53.3 shows the subsequent expansion of this framework to extend LRNs to include >200,000 physician offices as rapid testing sites for point-of-care waived diagnostic kits as a primary frontline interface and a main source of surveillance data for public health and patient care (50). Increasingly, pharmacies and nurse practitioners are doing rapid near-patient testing, and they should also be included in national laboratory networks. The vision was to create a fully integrated and coordinated laboratory network in every state, managed and coordinated by the state public health laboratory.

Marshall and colleagues (50) suggest that building national laboratory networks is a major cross-cultural exercise that should focus on the core functions and capabilities of state public health laboratories, including assessing and monitoring laboratory capacities, increasing coordination and communication across sectors, building partnerships between public and private laboratories, developing the laboratory workforce through training and education, and promoting laboratory standards as well as biosafety (50). However, breaking down traditional working relationships within the LRN model requires a strong network leadership and ongoing collaboration to build strong partnerships and working relationships among the various sectors. Inherent organizational, administrative, and cultural barriers exist between the "public health system" and a "frontline healthcare system" that is designed and operated to focus on providing individual patient care. To establish and sustain a robust LRN, therefore, public health needs to view itself as part of a larger "healthcare system" focused on both population-based and individual well-being, while physician offices and public and private laboratories also need to see themselves as part of the "public health system." Although some U.S. jurisdictions have made good progress towards creation of local LRNs (49), breaking down silos between laboratory sectors is an exercise in nation building that will require a sustained effort over years if not decades. Special governmental funding and project coordination will be required to make full integration and coordination of national laboratory systems a reality in many developed countries prior to the next pandemic.

Because laboratory infrastructure for routine clinical care support is lacking in many remote and resource-limited settings, the ability of laboratories to provide support for outbreak testing is sorely curtailed. Comprehensive analyses of the challenges and gaps that limit access to pathology and laboratory medicine in low-income and middle-income countries have been reported (4, 5, 25, 51).

本书版权归John Wiley & Sons Inc.所有

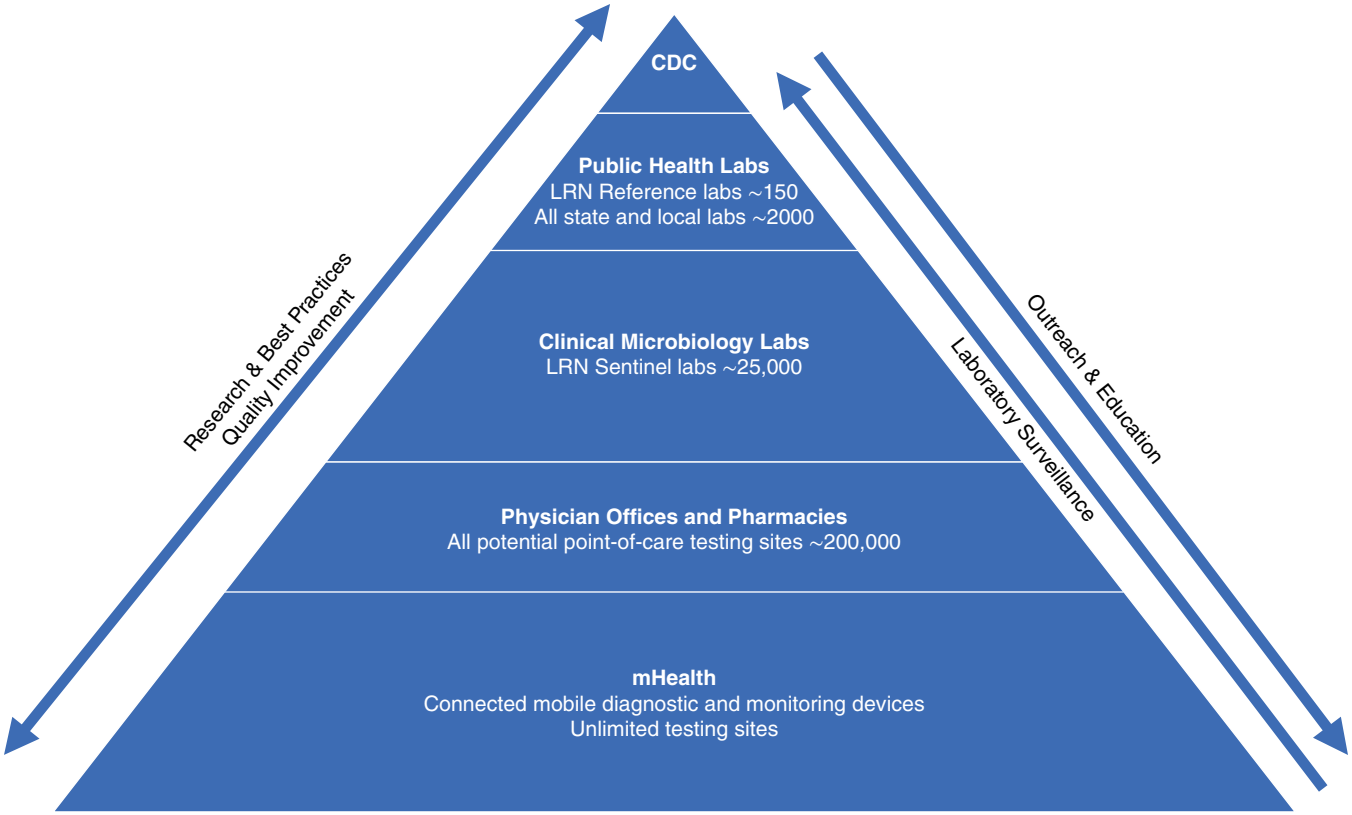


Figure 53.3 Expansion of Laboratory Response Networks (LRNs) to build a National Laboratory System in the United States (adapted from reference 49).

These include but are not limited to the absence of essential infrastructure, laboratory supplies, basic equipment, skilled personnel, supply chain management, and equipment maintenance, as well as to inadequate quality management systems, lack of government standards for laboratory testing, and continued reliance on empirical treatment. Global inequities in access to laboratory service have since been improved by global investment, advocacy, laboratory innovation, and sustained commitments to investment in laboratory medicine efforts in some jurisdictions (4, 5). Global investments by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund for AIDS, Tuberculosis and Malaria, and the World Bank have substantially improved laboratory support for these diseases (52). Strong political advocacy by regional commitments, such as the WHO Regional Office for Africa and the African Society for Laboratory Medicine, has also brought needed investment in laboratory medicine in this region (5). Laboratory quality and reliability have been considerably strengthened through flagship programs in Africa such as Strengthening Laboratory Management Towards Accreditation (SLMTA) and Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) (5). As of 2018, 49 countries including 23 in sub-Saharan Africa have implemented the SLMTA program, >5,000 people have been trained, and 54 of 1,150 SMTA laboratories have achieved accreditation to International Organization for Standardization (ISO) 15189 standards (5). However, systemic lack of investment in testing means that basic diagnostic capacity is still available to only 1% of primary-care clinics in many low- and middle-income countries.

Building a robust mHealth system within resource-limited settings is likely the way forward, provided the previously discussed limitations can be solved. Integration of point-of-care diagnostics into national laboratory tiered networks that are focused on connectivity for rapid transmission of test results would greatly facilitate and enhance global diagnostics access and capabilities worldwide. Additionally, the liaison and collaboration of diagnostics and healthcare personnel need to be strengthened within well-designed clinical care pathways applicable to different geographic locations to improve uptake and optimized use of laboratory test results.

Future Directions

Global investment in diagnostics and laboratory systems is required to maintain the progress of the past decade and to capitalize on translating the political attention to

本书版权归John Wiley & Sons Inc.所有

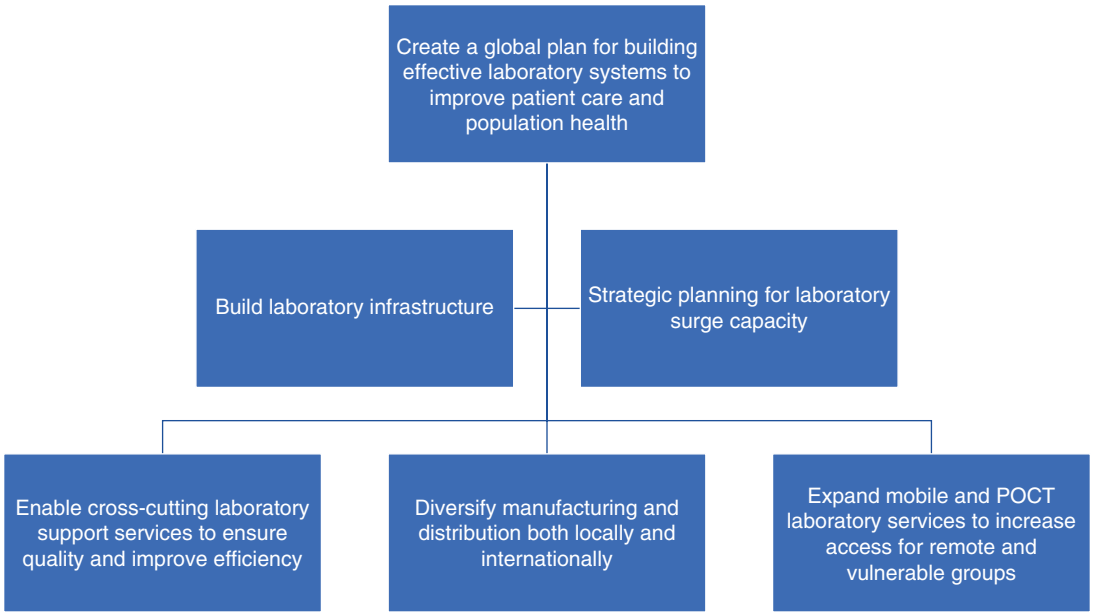


Figure 53.4 Improving global health through laboratory preparedness.

COVID-19 testing into action for global health (33). The priorities for developing a global health diagnostics program are outlined in Fig. 53.4. Global health diagnostics multisector partnerships (i.e., governments, academia, and industry) should prioritize innovative test development for WHO-priority known and unknown pathogens with outbreak potential (10, 33, 53). Core laboratory capabilities for diagnostic infectious diseases testing need to be urgently addressed in developed and resource-limited settings by the conjoint efforts of governments, healthcare systems, academia, and industry. But how does the world ensure diagnostics preparedness for the next pandemic? Perkins and colleagues advocate for the establishment of new partnering models to ensure effective surveillance-response approaches and diagnostic preparedness, in conjunction with international bodies including the WHO (10). To this end, a dedicated diagnostic product development effort has been formed, coordinated by the Foundation for Innovative New Diagnostics (FIND) and based on collaborations with the Institut Pasteur and other key diagnostic partners working under the auspices of the Coalition for Epidemics and Preparedness Innovations (CEPIdx) (10, 33). This group has a specific goal of ensuring that diagnostic outbreak needs are comprehensively addressed, as outlined in Fig. 53.1. A collective call to action, however, will require a tightly coordinated effort among governments, donor organizations, and public-private partnerships that include representatives from the medical/scientific laboratorians, academia, and industry all working together within this context towards common goals. Strong national and regional health authority leadership is also crucial for increasing domestic funding for building robust laboratory systems capable of supporting sustained capacity during a pandemic response while maintaining routine services. Perhaps the lessons learned from past outbreaks and the ongoing COVID-19 pandemic will have finally shone a spotlight on the critical importance of laboratory systems so that sustained resourcing is elevated as a top priority within global healthcare systems.

SUMMARY

Sustained global efforts are critical for building robust laboratory systems worldwide to meet the demands of the next pandemic. Significant investment into diagnostic development, infrastructure, human resource management, and the creation of well-coordinated regional, national, and global laboratory networks is urgently needed. Existing management silos between various parts of the system, though challenging, must be streamlined to coordinate a seamless integrated working relationship among all sectors within a coordinated laboratory response network. Coordinated programs must be in place for implementation of new outbreak tests including technology, biosafety, and validation training and assistance provided by public health personnel to all types of diagnostic laboratories (i.e., public and private) to facilitate regional testing surge capacity. Mobile health programs as part of well-established clinical care pathways, supported by field-and home-based connected digital diagnostics, should become the forefront of comprehensive care and public health response, particularly for remote, vulnerable, and resource-limited populations. While individual laboratory administrators should perform

本书版权归John Wiley & Sons Inc.所有

SWOT analysis of their local system preparedness, national and international programs are urgently needed to address laboratory preparedness on a global scale.

KEY POINTS

- Laboratory preparedness for large outbreaks and pandemics is a critical part of an overall response plan.
- Healthcare and laboratory systems worldwide were not adequately prepared for the COVID-19 pandemic.
- Diagnostics development and preemptive manufacturing and distribution of essential equipment, reagents, and supplies including PPE are required for laboratory systems to efficiently reach surge capacity.
- Sustained investment in laboratory systems is essential for pandemic readiness.
- Comprehensive human resource planning should ensure the availability of highly skilled laboratory staff, particularly those with molecular expertise and training.
- Mobile health (mHealth) programs equipped with mobile testing devices as part of well-established clinical care pathways should become the forefront of public health and comprehensive care response.
- Regional, national, and global laboratory response networks are required to coordinate pandemic testing efforts.

GLOSSARY

Armored RNA RNA of a defined nucleotide sequence that is produced in a way that completely protects it from plasma RNase degradation. Armored RNA controls are commercially available for several clinically important viruses and are used as stable, reliable controls in diagnostic assays testing for the presence of a particular virus (e.g., SARS-CoV-2).

College of American Pathologists (CAP) CAP is a member-based physician organization founded in 1946 in the United States. CAP comprises approximately 18,000 board-certified member pathologists. The organization serves patients, pathologists, and the public by fostering and advocating best practices in pathology and laboratory medicine, including the administration of a world-renowned external quality assurance program for clinical laboratory proficiency testing and CAP accreditation against specific standards of practice.

COVID-19 Coronavirus disease (COVID-19) is an infectious disease caused by the SARS-CoV-2 virus or severe acute respiratory syndrome beta-coronavirus 2. This novel beta-coronavirus caused a global pandemic in 2019–2022.

Centers for Disease Control and Prevention (CDC) The CDC is the national public health agency of the United States. The CDC is a federal agency under the Department of Health and Human Services, and its headquarters is in Atlanta, Georgia.

Data dashboards A dashboard is a way of displaying various types of data in a visual format. It is intended to convey different but related information about various metrics in an easy-to-digest but readily updated form (i.e., figures, tables, timelines, etc.).

Food and Drug Administration (FDA) The U.S. FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

Infection surveillance Targeted surveillance of specific types of infection of interest, usually those with heightened risk of transmissibility in a given environment such as the community, hospitals, or long-term-care facilities. Active infection surveillance of a specific type of infection involves diagnosing cases against a specific set of epidemiological, clinical, and laboratory criteria for confirmed, probable, and possible cases of a disease under surveillance in order to determine the overall incidence and prevalence rates in a given population, its transmissibility, and the specific group(s) most at risk.

Information technology (IT) IT is the use of computers, mobile devices, and other hardware and software to create, clean, store, retrieve, and exchange all kinds of data and information in an organized and efficient manner. IT is a critical component of modern information and communication strategies for pandemic response.

Mobile laboratory service A type of laboratory service where a mobile vehicle may collect the required specimen(s) to perform clinical laboratory testing at a centralized location or even a mobile vehicle that houses a fully equipped laboratory certified to perform a specific menu of tests near patient locations. Mobile vans are usually operated as part of a larger centralized clinical laboratory service, so that highly skilled personnel perform specimen collection and testing and tests are performed to the same quality-assured standard as would occur in the centralized facility.

Outbreak An outbreak is a sudden increase in occurrences of a disease when case numbers are more than normal expectancy for the location or season. Localized outbreaks may affect a small and specific epidemiologic group or spread to impact large numbers of people in adjoining jurisdictions, or an entire continent and beyond.

Pandemic An outbreak of a disease that occurs over a wide geographic area (such as multiple countries or continents) and typically affects a significant proportion of the population: a pandemic outbreak of a disease (e.g., the great influenza pandemic of 1918; the recent COVID-19 pandemic of 2020–2022).

Point-of-care testing (POCT) POCT involves testing or screening for specific acute infectious or chronic diseases near the patient or at the point of patient care outside a centralized laboratory. Testing is performed by trained personnel, and home-based testing by patients is not included in POCT programs. A major advantage of a POCT program is the production of actional results close to the patient to expedite patient care.

本书版权归John Wiley & Sons Inc.所有

Public health The science of protecting and improving the health of people and their communities. This work is achieved by promoting healthy lifestyles, researching disease and injury prevention, and detecting, preventing, and responding to infectious diseases. Overall, public health is concerned with protecting the health of entire populations. These populations can be as small as a local neighborhood, or as big as an entire country or region of the world.

Privacy protection Electronic personal and health information that one needs to keep private from other people, hackers, companies, and government organizations and other groups must be protected online by various measures including passwords, authentication processes, and policies about what, when, and who can obtain such data.

Real-time polymerase chain reaction PCR (polymerase chain reaction) is a molecular biology technique that monitors the amplification of a targeted DNA molecular during the PCR reaction. A real-time PCR test monitors the accumulation of a specific amplicon during the procedure, compared to a conventional PCR test where the amplicons are only measured at the end by running a gel. Real-time PCR tests can be semiquantitative or quantitative.

WHO ASSURED and REASSURED test criteria The World Health Organization ASSURED (Affordable, Sensitive, Specific, User-friendly, Rapid, Equipment-free, and Delivered) criteria for the ideal characteristics of deployed point-of-care diagnostic tests in developing nations. These criteria have since been revised to REASSURED (Real-time connectivity and Ease of collection being added to the existing ASSURED criteria) due to advancements in digital technologies and POCT devices that enable collection of small fingerstick blood samples (i.e., blood glucose monitoring). Advanced POCT devices that adhere to the REASSURED criteria are in use in both developing and developed countries.

WHO Priority Pathogens List The World Health Organization pandemic pathogen priority list for targeted research and development was first published in 2017 and most recently updated in 2018. The prioritization process identified several viruses deemed to have a higher risk for causing a large outbreak or pandemics. The current list includes the viruses causing COVID-19, Crimean-Congo hemorrhagic fever, Ebola virus disease, Marburg virus disease, Lassa fever, Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS), Nipah and henipaviral diseases, Rift Valley fever, and Zika fever, and the pathogen causing Disease X. The WHO list is currently in the process of being updated.

REFERENCES

1. **Wilson ML, Gradus S, Zimmerman SJ**. 2010. The role of local public health laboratories. *Public Health Rep* **125**(Suppl 2):118–122.

2. **Reller LB, Weinstein MP, Peterson LR, Hamilton JD, Baron EJ, Tompkins LS, Miller JM, Wilfert CM, Tenover FC, Thomson RB Jr.** 2001. Role of clinical microbiology laboratories in the management and control of infectious diseases and the delivery of health care. *Clin Infect Dis* **32**:605–610.

3. **Cantón R.** 2005. Role of the microbiology laboratory in infectious disease surveillance, alert and response. *Clin Microbiol Infect* **11**(Suppl 1):3–8.

4. **Wilson ML, Fleming KA**. 2017. Improving global access to diagnostic testing. *Am J Clin Pathol* **147**:6–7.

5. **Nkengasong JN, Yao K, Onyebujoh P**. 2018. Laboratory medicine in low-income and middle-income countries: progress and challenges. *Lancet* **391**:1873–1875.

6. **Nkengasong JN, Nsubuga P, Nwanyanwu O, Gershy-Damet GM, Roscigno G, Bulterys M, Schoub B, DeCock KM, Birx D**. 2010. Laboratory systems and services are critical in global health: time to end the neglect? *Am J Clin Pathol* **134**:368–373.

7. **Mitchell SL, St George K, Rhoads DD, Butler-Wu SM, Dharmarha V, McNult P, Miller MB**. 2020. Understanding, verifying, and implementing emergency use authorization molecular diagnostics for the detection of SARS-CoV-2 RNA. *J Clin Microbiol* **58**:e00796–20.

8. **Burnham CD, Kwon JH, Burd EM, Campbell S, Iwen PC, Miller MB**. 2017. Are we there yet? Laboratory preparedness for emerging infectious diseases. *Clin Chem* **63**:807–811.

9. **Walker NF, Whitty CJ**. 2015. Tackling emerging infections: clinical and public health lessons from the West African Ebola virus disease outbreak, 2014–2015. *Clin Med (Lond)* **15**:565a.

10. **Perkins MD, Dye C, Balasegaram M, Bréchot C, Mombouli JV, Røttingen JA, Tanner M, Boehme CC**. 2017. Diagnostic preparedness for infectious disease outbreaks. *Lancet* **390**:2211–2214.

11. **Moon S, Sridhar D, Pate MA, Jha AK, Clinton C, Delaunay S, Edwin V, Fallah M, Fidler DP, Garrett L, Goosby E, Gostin LO, Heymann DL, Lee K, Leung GM, Morrison JS, Saavedra J, Tanner M, Leigh JA, Hawkins B, Woskie LR, Piot P**. 2015. Will Ebola change the game? Ten essential reforms before the next pandemic. The report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola. *Lancet* **386**:2204–2221.

12. **Faye O, Boëlle PY, Heleze E, Faye O, Loucoubar C, Magassouba N, Soropogui B, Keita S, Gakou T, Bah HI, Koivogui L, Sall AA, Cauchemez S**. 2015. Chains of transmission and control of Ebola virus disease in Conakry, Guinea, in 2014: an observational study. *Lancet Infect Dis* **15**:320–326.

13. **Hill CE, Burd EM, Kraft CS, Ryan EL, Duncan A, Winkler AM, Cardella JC, Ritchie JC, Parslow TG**. 2014. Laboratory test support for Ebola patients within a high-containment facility. *Lab Med* **45**:e109–e111.

14. **Centers for Disease Control and Prevention.** 2021. Ebola disease: 2014–2016 Ebola outbreak distribution in West Africa. https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/distribution-map.html. Accessed 13 September 2023.

15. **Nishiura H, Chowell G**. 2014. Early transmission dynamics of Ebola virus disease (EVD), West Africa, March to August 2014. *Euro Surveill* **19**(36):20894.

16. **Chowell G, Nishiura H**. 2014. Transmission dynamics and control of Ebola virus disease (EVD): a review. *BMC Med* **12**:196.

17. **Kelly-Cirino CD, Nkengasong J, Kettler H, Tongio I, Gay-Andrieu F, Escadafal C, Piot P, Peeling RW, Gadde R, Boehme C**. 2019. Importance of diagnostics in epidemic and pandemic preparedness. *BMJ Glob Health* **4**(Suppl 2):e001179.

本书版权归John Wiley & Sons Inc.所有

18. Toney D, Pentella M, Blank E, Becker S. 2021. Creating a blueprint for the future: lessons learned from public health laboratories in the COVID-19 response. COVID-19 and Public Health: Looking Back, Moving Forward. *J Public Health Manag Pract* **27**(Suppl 1): S101–S105.

19. Duś-Ilnicka I, Szymczak A, Małodobra-Mazur M, Tokarski M. 2021. Role of laboratory medicine in SARS-CoV-2 diagnostics. Lessons learned from a pandemic. *Healthcare (Basel)* **9**:915.

20. Nguyen T, Wolff A. 2021. Rapid diagnostics for SARS-CoV-2 virus: point-of-care testing and lessons learned during the pandemic. *Bioanalysis* **13**:1165–1167.

21. Gharizadeh B, Yue J, Yu M, Liu Y, Zhou M, Lu D, Zhang J. 2021. Navigating the pandemic response life cycle: molecular diagnostics and immunoassays in the context of COVID-19 management. *IEEE Rev Biomed Eng* **14**:30–47.

22. Chugh H, Samaan G, Resnikoff T, Bergeri I, Barragan J, Dueger E. 2020. The Pandemic Influenza Preparedness (PIP) Framework: strengthening laboratory and surveillance capacities in the Western Pacific Region, 2014–2017. *Western Pac Surveill Response J* **11**:32–35.

23. Henry B, Canadian Pandemic Influenza Preparedness (CPIP) Task Group. 2018. Canada's Pandemic Influenza Preparedness: laboratory strategy. *Can Commun Dis Rep* **44**:10–13.

24. Church DL, Naugler C. 2019. Benefits and risks of standardization, harmonization and conformity to opinion in clinical laboratories. *Crit Rev Clin Lab Sci* **56**:287–306.

25. Wilson ML, Fleming KA, Kuti MA, Looi LM, Lago N, Ru K. 2018. Access to pathology and laboratory medicine services: a crucial gap. *Lancet* **391**:1927–1938.

26. Wilson ML. 2008. Assuring the quality of clinical microbiology test results. *Clin Infect Dis* **47**:1077–1082.

27. Leo S, Cherkaoui A, Renzi G, Schrenzel J. 2020. Mini review: clinical routine microbiology in the era of automation and digital health. *Front Cell Infect Microbiol* **10**:582028.

28. Naugler C, Church DL. 2019. Automation and artificial intelligence in the clinical laboratory. *Crit Rev Clin Lab Sci* **56**:98–110.

29. Forbes BA. 2003. Introducing a molecular test into the clinical microbiology laboratory: development, evaluation, and validation. *Arch Pathol Lab Med* **127**:1106–1111.

30. Burd EM. 2010. Validation of laboratory-developed molecular assays for infectious diseases. *Clin Microbiol Rev* **23**:550–576.

31. Moehling TJ, Choi G, Dugan LC, Salit M, Meagher RJ. 2021. LAMP diagnostics at the point-of-care: emerging trends and perspectives for the developer community. *Expert Rev Mol Diagn* **21**:43–61.

32. Vandenberg O, Martiny D, Rochas O, van Belkum A, Kozlakidis Z. 2021. Considerations for diagnostic COVID-19 tests. *Nat Rev Microbiol* **19**:171–183.

33. Boehme C, Hannay E, Pai M. 2021. Promoting diagnostics as a global good. *Nat Med* **27**:367–368.

34. US Food and Drug Administration. 2023. In vitro diagnostics EUAs - molecular diagnostic tests for SARS-CoV-2. https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2. Accessed 12 September 2023.

35. US Food and Drug Administration. 2023. Guidance documents related to coronavirus disease 19 (COVID-19). https://www.regulations.gov/document/FDA-2020-D-0987-0074. Accessed 12 September 2023.

36. Richards M, Hong Y, Butz K. 2021. Emergency use authorization and antigen diagnostic tests for COVID-19: challenges and future trends. *The Evidence Forum*. https://www.evidera.com/wp-content/uploads/2021/05/EFSpr21_A04-RichardsM01-EUA.pdf. Accessed 22 July 2023.

37. Asadzadeh A, Pakkhoo S, Saeidabad MM, Khezri H, Ferdousi R. 2020. Information technology in emergency management of COVID-19 outbreak. *Inf Med Unlocked* **21**:100475.

38. Ye Q, Zhou J, Wu H. 2020. Using information technology to manage the COVID-19 pandemic: development of a technical framework based on practical experience in China. *JMIR Med Inform* **8**:e19515.

39. Budd J, Miller BS, Manning EM, Lampos V, Zhuang M, Edelstein M, Rees G, Emery VC, Stevens MM, Keegan N, Short MJ, Pillay D, Manley E, Cox IJ, Heymann D, Johnson AM, McKendry RA. 2020. Digital technologies in the public-health response to COVID-19. *Nat Med* **26**:1183–1192.

40. Wood CS, Thomas MR, Budd J, Mashamba-Thompson TP, Herbst K, Pillay D, Peeling RW, Johnson AM, McKendry RA, Stevens MM. 2019. Taking connected mobile-health diagnostics of infectious diseases to the field. *Nature* **566**:467–474.

41. Wilkerson ML, Henricks WH, Castellani WJ, Whitsitt MS, Sinard JH. 2015. Management of laboratory data and information exchange in the electronic health record. *Arch Pathol Lab Med* **139**:319–327.

42. Sim I. 2019. Mobile devices and health. *N Engl J Med* **381**:956–968.

43. Fonjungo PN, Boeras DI, Zeh C, Alexander H, Parekh BS, Nkengasong JN. 2016. Access and quality of HIV-related point-of-care diagnostic testing in global health programs. *Clin Infect Dis* **62**:369–374.

44. Kpokiri EE, Marley G, Tang W, Fongwen N, Wu D, Berendes S, Ambil B, Loveday SJ, Sampath R, Walker JS, Matovu JKB, Boehme C, Pai NP, Tucker JD. 2020. Diagnostic infectious diseases testing outside clinics: a global systematic review and meta-analysis. *Open Forum Infect Dis* **7**:ofaa360.

45. Xing W, Wang J, Zhao C, Wang H, Bai L, Pan L, Li H, Wang H, Zhang Z, Lu Y, Chen X, Shan S, Wang D, Pan Y, Weng D, Zhou X, Huang R, He J, Jin R, Li W, Shang H, Zhong N, Cheng J. 2021. A highly automated mobile laboratory for on-site molecular diagnostics in the COVID-19 pandemic. *Clin Chem* **67**:672–683.

46. Mahshid SS, Flynn SE, Mahshid S. 2021. The potential application of electrochemical biosensors in the COVID-19 pandemic: a perspective on the rapid diagnostics of SARS-CoV-2. *Biosens Bioelectron* **176**:112905.

47. Raimann FJ, Piekarski F, Adam EH, Zacharowski K, Neef V. 2021. Safety considerations for the use of point-of-care diagnostics during SARS-CoV-2 pandemic. *J Clin Lab Anal* **35**:e23631.

48. Merazzo KJ, Totoricaguena-Gorriño J, Fernández-Martín E, Del Campo FJ, Baldrich E. 2021. Smartphone-enabled personalized diagnostics: current status and future prospects. *Diagnostics (Basel)* **11**:1067.

本书版权归John Wiley & Sons Inc.所有

49. Kirk CJ, Shult PA. 2010. Developing laboratory networks: a practical guide and application. *Public Health Rep* **125**(Suppl 2): 102–109.

50. Marshall SA, Brokopp CD, Size T. 2010. Leadership principles for developing a statewide public health and clinical laboratory system. *Public Health Rep* **125**(Suppl 2):110–117.

51. Horton S, Sullivan R, Flanigan J, Fleming KA, Kuti MA, Looi LM, Pai SA, Lawler M. 2018. Delivering modern, high-quality, affordable pathology and laboratory medicine to low-income and middle-income countries: a call to action. *Lancet* **391**:1953–1964.

52. Leeper SC, Reddi A. 2010. United States global health policy: HIV/AIDS, maternal and child health, and The President's Emergency Plan for AIDS Relief (PEPFAR). *AIDS* **24**:2145–2149.

53. World Health Organization. 2023. Prioritizing diseases for research and development in emergency contexts. https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts. Accessed 12 September 2023.

54. Leydesdorff L, Etzkowitz H. 1998. The Triple Helix as a model for innovation studies. *Sci Policy* **25**(3):195–203.

本书版权归John Wiley & Sons Inc.所有

Index

Note: Page numbers in *italics* refer to *figures*; those in **bold** to **tables**

A

AAB, *see* American Association of Bioanalysts
AABB, *see* American Association of Blood Banks (now the Association for the Advancement of Blood and Biotherapies)
AAMRO, *see* American Association of Medical Review Officers
ABIM, *see* American Board of Internal Medicine Foundation
ableism, 164
ABN, *see* Advance Beneficiary Notice
ACA, *see* Affordable Care Act of 2010
academic medical centers (AMCs), 83, 698
acceptance
  in communication, 15
  criteria, 295
  in decision making, 11
access-based positioning, 402
access to draw sites and patient service centers, 562–563
accountable care organizations (ACOs), 74, 83, 329, 453, 464, 619
accounts payable, 539
accounts receivable, 439, 537–539
accreditation, 29–33, 203, 204, 619, 646
  ISO 15189, 275–277
  point-of-care testing, 300
Accreditation Commission for Health Care (ACHC), 30
Accreditation Council for Graduate Medical Education (ACGME), 61
accrediting agencies, 619
accrual accounting, 439
accuracy, 265, 696
ACGME, *see* Accreditation Council for Graduate Medical Education
ACHC, *see* Accreditation Commission for Health Care
achievement conflicts, 145
ACOs, *see* accountable care organizations
action collaborative on clinician well-being and resilience, 61
active listener, 129
active shooter/hostage response, 390
activity fit, 404
actual cost, 418
actuarial data, 68
ad hoc communication, 630
ADA, *see* Americans with Disabilities Act of 1990
adapting communication styles, 132, **132**
add-on code edits, 481, 486
add-on tests, 556, 567
adjudication (of a claim), 453, 486
Adkar model of change management, 153–155, *154*
ADLT, *see* advanced diagnostic laboratory test
administration *vs.* management, 3–4
administrative decisions, 10
administrative interest, 516–518
administrative law judge, 237
Administrative Services Only (ASO), 70
Administrative Simplification and Compliance Act Of 2001, 478
admission/discharge/transfer (ADT) interface, 289
ADT, *see* Admission/discharge/transfer interface
advance beneficiary notice (ABN), 325, 453, 460, 486, 524, 555–556, 567
Advanced Alternative Payment Methods (APM), 43, 619
advanced diagnostic laboratory test (ADLT), 447, 453, 471
advisory opinions, 502
advisory panel on clinical laboratory diagnostic tests, 471
aerosol, 361
  transmission, 713
Aetna, 55
affiliation, 121
Affordable Care Act of 2010 (ACA), 42, 54, 329, 450, 481, 497, 498, 642
AFL-CIO, *see* American Federation of Labor–Congress of Industrial Organizations
age/sex rating, 68
Agency for Healthcare Research and Quality (AHRQ), 117, 601
agenda
  consent, 138
  development of, 137, *138*
AHRQ, *see* Agency for Healthcare Research and Quality
AI, *see* artificial intelligence
airborne transmission, 361
AKS, *see* Anti-Kickback Statute
algorithm, 79
allowances, 539
ally doctrine, 237
alternative payment model (APM), 74
alternatives, in decision making, 11–12
AMA, *see* American Medical Association
ambulatory payment classification (APC), 17, 18, 393, 394, 453, 465, 479, 484, 486
AMCs, *see* academic medical centers
American Association for Laboratory Accreditation (A2LA), 30
American Association of Bioanalysts (AAB), 33
American Association of Blood Banks (now the Association for the Advancement of Blood and Biotherapies [AABB]), 26
American Association of Medical Review Officers (AAMRO), 249
American Board of Internal Medicine (ABIM) Foundation, 59, 62, 667
American Federation of Labor–Congress of Industrial Organizations (AFL-CIO), 231, 237
American Hospital Association Reports, 202

本书版权归John Wiley & Sons Inc.所有

American Medical Association (AMA), 453
CPT codebook, 499
equal access to healthcare, 56
American Medical Technologists (AMT), 33
American National Standards Institute (ANSI), 41, 486
American Osteopathic Association (AOA), 26, 30
American Recovery and Reinvestment Act, 46, 56, 62, 323, 660
American Society for Clinical Laboratory Science (ASCLS), 33, 202, 203
American Society for Clinical Pathology (ASCP), 108, 203, 204
board of certification (BOC), 166
certification by, 33
American Society for Histocompatibility and Immunogenetics (ASHI), 26, 30
American Society for Microbiology (ASM), 204, 602
Americans with Disabilities Act of 1990 (ADA), 171, 177, 187
AMT, *see* American Medical Technologists
"analysis paralysis," 11
analyte, 265
analyte-specific reagents, 260, 326, 329, 453–454, 486
analytic activity, 329
analytic epidemiology, 713
analytical method, 265
analytical range, 265
anatomic pathology, 558, 698
animal signals, for early warning, 719–720
ANSI, *see* American National Standards Institute
Anthem, 55
Anthropocene, 718, 723, 724
Anthropocene Epoch, 712
Anti-Kickback Statute (AKS), 399, 456, 486
antibiogram, 295
antigen, 714
antimicrobial stewardship, 58
antiquity, epidemics of, 704–709
antitrust laws, 54–55
AOA, *see* American Osteopathic Association
APC, *see* Ambulatory Payment Classification; Association of Pathology Chairs
APM, *see* Alternative Payment Model
application software, 2953
applied epidemiology, 714
appraisals, *see* performance appraisals
appraiser, 190
appropriate use criteria, 486
appropriate use edits, 481
arbitration, 237
Aristotle, 595
armored RNA, 759
ARR, *see* average rate of return
arterial blood gases, 566
artificial intelligence (AI), 604, 692–693, 739
ASC X12 (accredited standards committee) version 5010, 478
ASCLS, *see* American Society for Clinical Laboratory Science
ASCP, *see* American Society for Clinical Pathology
ASHI, *see* American Society for Histocompatibility and Immunogenetics
ASM, *see* American Society for Microbiology
ASO, *see* Administrative Services Only
assay performance, 336
assets, 439, 539
management ratios, 439
assignment, 454
Association for the Advancement of Blood and Biotherapies (AABB), 30
Association of Pathology Chairs (APC)
pipeline subcommittee of the APC advocacy committee, 54
assured test criteria, 760
attack rate, 714
attention, in communication, 15
attribution theory, 122
A2LA, *see* American Association for Laboratory Accreditation
audits and auditing, 502
in outreach programs, 557
remittance advice, 485
authenticity, 100–102
definition of, 100
importance of context, 101
knowing yourself, 100–101
path to, 101–102
situational response, 101
authoritarian leaders and managers, 5
authorization, 44–45
authorization cards, 233, 237
required percentage, 238
automated laboratory assays, 580–581
automation, 208, 336, 693–695
autonomous work teams, 214
autoverification, 286, 302, 676, 685
average costs, 418, 439
average rate of return (ARR), 539, 547–548

B

Baby Boomers, 19, 162
behaviors, **112**
communication preferences, **113**
cultural preferences and values, **113**
technology styles, **113**
work style, **113**, **163**
workplace strengths, **112**
workplace struggles, **112**
Bacon, Francis, 333
bad debt, 439, 469, 539
balance sheet, 439, 507
Balanced Budget Act of 1997 (BBA '97), 454, 462
Balanced Budget Refinement Act of 1999 (BBRA '99), 454
bargaining topics, 238
bargaining unit, 233, 238
BARS, *see* behaviorally anchored rating scale
basic reproduction number, 714, 739
batch size, 336
BBA '97, *see* Balanced Budget Act of 1997
BBRA '99, *see* Balanced Budget Refinement Act of 1999
bedside testing, *see* point-of-care testing (POCT)
behavioral theory of management, 5–6
behaviorally anchored rating scale (BARS), 189
Bell, Alexander Graham, 343
Belmont report (1979), 586
benchmark, 619
benchmarking, 609–619
challenges in executing, 614–616
comparability in, 614–615
competitive, 619
cost accounting in, 615
COVID-19 pandemic, effects of, 616
data collection and analysis, 613
external, 619
indicators for, 615–616
internal, 611, 619
interpretation of, 613–614
laboratory performance measurement in, 616–618
metrics selection in, 612–613
performance monitoring data in, 613–616
plans, development and implementation of, 613
prioritization in, 612
sample metrics, **616**
selection bias in, 614–615
strategic, 610
types of, 611–612
beneficiary documents, 485
Bernoulli, Daniel, 706
best practice alert, 671
bias, 265
bidirectional interface, 295

本书版权归John Wiley & Sons Inc.所有

Big 5 personality traits, 146, **146**
big data, 739
billable test, 486, 619
billed test, 619
billing, 19, 460–467, 539
  capitated arrangement, 466
  code, 539
  direct, 67
  direct client, 538–539
  fee-for-service arrangement, 466
  interface, 290
  payor mix in, 462–464
  provider mix in, 461
  terms of coverage for, 464–465
bioinformatics
  impact on pathology, 79–80
biological hazards, 38, 344
  spill kit sample, 367
biological safety cabinets, 353
biological spill cleanup procedure, 367
biosafety, 756–757
biostatistics
  descriptive statistics, 599
  diagnostic studies, challenges for, 600–601
  inferential statistics, 599–600
bioterrorism agents, 645–646
biotype, 714
biovar, 714
Black Act, *see* Fair Labor Standards Act of 1938 (FLSA)
Black Belts, in Six Sigma, 9
blood banking, 293–294
blood-borne pathogens, 361
  exposure control plan requirements, **39**
  occupational exposure to, **39**
blood products, 60
blood transfusion, 681–682, **682**; *see also* transfusion medicine
  regulatory requirements for, 34–36
BLS, *see* Bureau of Labor Statistics
Blumenthal, David, 285
body language, 127–128, 131
bomb threat, 380
book costs, 539
bottom-up customer focus, 86
bottom-up microcosting, 539
boutique-laboratory testing, 403
BPCI, *see* Bundled Payments of Care Initiatives
Breach Notification Rule, 45
break-even analysis, 420
break-even or crossover point, 439, 539
budget, *see also* budgeting
  capital, 18–19, 429
  examples, 430
  expense, 429
  operating, 18, 427–429
  revenue, 429
  statistical, 429
  types of, 427–430
budgeting, 18, 427–430; *see also* budget
  activity-based, 18
  incremental, 18, 440
  process, 429–30
  zero-based, 18
bundled payment, 68
Bundled Payments of Care Initiatives (BPCI), 486
bundling, 454, 486
Bureau of Labor Statistics (BLS), 40, 162, 203, 237
bureaucracy theory of management, 7
burnout
  definition of, 108–109
  drivers of, **110**
  strategies for assessing and reducing, 109–111
business plan, 520–521, 524
business strategy, 396–397
  development of, 397–398
  maintenance of, 397–398
Byron, Lord George Gorden Noel, 460

C

cabal, 414
CAC, *see* contractor advisory committee
calibration, 265
candidate selection, in hiring process, 172–173
CAP, *see* College of American Pathologists
CAP-FDT, *see* College of American Pathologists Forensic Drug Testing
cap workload recording method, 206
capital, 439
  acquisition, in cost accounting, 420–427
  budget, 18–19, 429, 439
  item, 539
  lease, 439, 539
capitated arrangement billing, 466
capitated payments, 471–472
capitated services, 450
capitation, 68–69, 394, 439, 454
  contract, 69, 420
carcinogen, 361
care pathway, 604
carrier, 714
carve out, 454
case fatality rate, 714
cash accounting, 439
cash budget, 439
cash flow, 439, 540
cash flow statements, 439, 508
category A substance, 361
  shipper's declaration for, 359, 371
category B substance, 361
CBA, *see* cost-benefit analysis
CBCS, *see* complete blood counts
CBER, *see* Center for Biologics Evaluation and Research
CBJD, *see* criteria-based job description
CDC, *see* Centers for Disease Control and Prevention
CDHP, *see* consumer-driven health plan
CDS, *see* clinical decision support
CEA, *see* cost-effectiveness analysis
CEHRT, *see* certified electronic health record technology
ceiling limit, 361
cellular therapies, 36
Center for Biologics Evaluation and Research (CBER), 34
Centers for Disease Control and Prevention (CDC), 163, 649, 660, 719, 739, 759
  on HIV, 56
  Morbidity and Mortality Weekly Report, 41–42
  vaccine recommendations, **174**
Centers for Medicare and Medicaid Services (CMS), 329, 478, 524, 619, 649, 671, 685
  inspection by, 30
centralized testing, 16
certification
  ASCP, 33
  CLIA, **28**
  election, 238
  national qualifications, 31, 33
  personnel, 31–33
  states requiring, 33
certified EHR, 671
certified electronic health record technology (CEHRT), 685
certified union, 238
CGMP, *see* Current Good Manufacturing Practices
Champy, James, 84
change, 151–157; *see also* change management
  control, 291, 295
  definition of, 152
  drivers, in healthcare and clinical laboratories, **19**
  need for, 153
  psychology of, 152
  sources of, 153
  supporting laboratory staff through, 155–157
change management, 152–153
  auditing and reinforcing, 156–157
  case study, 158
  models of, 153–155
  resistance to change, 156

本书版权归John Wiley & Sons Inc.所有

charge-based reimbursement, 68
charge(s), 238, 468–473, 540
  calculation of, 468–469
  setting, 469
checklist adjectives evaluation, 189
chemical fume hoods, 353
chemical hazards, 38, 344–345
chemical hygiene plan, **38**
chemicals, safe handling of, **38**
chemistry, **679**
  advances in, 679–680
  laboratory automation, 680
  laboratory computerization, 680
Children's Health Insurance Program (CHIP), 44, 45, 454, 462
CHIP, *see* Children's Health Insurance Program
cholera, 707
Churchill, Sir Winston, 373
Cigna, 55
CIPS, *see* conflict-of-interest policies
civil disorder, 382
Civil False Claims Act, 486
Civil Monetary Penalties Law, 486
claim adjustment reason codes, 485
claims, 452–453, 486
  billing, 465–466
  denial management, 454
  versus invoice submission, 465
Class I device, 33
Class II device, 33
Class III device, 33
classical theory of management, 4–5
CLFS, *see* Clinical Laboratory Fee Schedule
CLIA, *see also* CLIA '67 (Clinical Laboratory Improvement Act of 1967); CLIA '88 (Clinical Laboratory Improvement Amendments of 1988)
  certificates, types of, **28**
  federal agency responsibility, **27**
  framework, 27
CLIA '67 (Clinical Laboratory Improvement Act of 1967), 26, 619
  framework, 27
CLIA '88 (Clinical Laboratory Improvement Amendments of 1988), 26, 67, 85, 329, 394, 619, 642–644, 649
  changes to CLIA and alternative approaches, 643
  competency assessment, 194
  complexity categories, 643
  education, 203
  framework, 27
  future regulatory climate under, 643–644
  ISO 15189 and, 275
  key amendments and recent requests, **26**
  laboratories exempt from, 31
  minimum personnel requirements, 166
  personnel requirements under, 31
  personnel responsibilities and qualifications under, **32**
  personnel standard, 643
  proposed changes to personnel requirements, 31
  quality control standards, 643
  waived testing, 643
CLIA-waived testing, 394
client, 295
client bill, 568
client relationship management, 532
client services, 562
Clinical and Laboratory Standards Institute (CLSI), 41, 203, 311, 329
  quality system essentials, **265**
clinical decision support, 56, 295
clinical laboratory consultation, 698
Clinical Laboratory Fee Schedule (CLFS), 44, 67, 454, 470, 649
  fee setting for new codes on, 470–471
clinical laboratory finances, brief history of, 19
Clinical Laboratory Improvement Act of 1967, *see* CLIA '67
Clinical Laboratory Improvement Amendments of 1988, *see* CLIA '88 (Clinical Laboratory Improvement Amendments of 1988)
clinical laboratory industry, structure of
  barriers to entry, 398–399
  beneficiary, 399
  competitors, concentration of, 398
  economies of scale, 399
  inpatient care, 400
  payor, 399
  powerful sellers and buyers, 399–400
  purchasing agent, 399
  restrictions on markups and kickbacks, 399
  substitute products, 400
  testing market, 398
Clinical Laboratory Management Association (CLMA), 204, 619
clinical laboratory scientist, 330
clinical laboratory workplace safety, 36–42
  additional resources, 41–42
  biological hazards, 38
  chemical hazards, 38
  clinical specimens, transportation of, 40
  elements of, **37**
  infectious hazards, 39–40
  physical hazards, 40–41
  risk assessments, 37–38
clinical pathology, 698
clinical pathway, 77
clinical scientist
  role of, 654–657
  workforce, future of, 652–658
clinical specimens, transportation of, 40
Clinton, Bill, 40
CLMA, *see* Clinical Laboratory Management Association
closed shop, 238
cloud computing, 287, 295
cloud LIS, 295
CLSI, *see* Clinical and Laboratory Standards Institute
cluster, 714
CMS, *see* Contractors Centers for Medicare and Medicaid Services
CMS-1450 (formerly UB-92), 486
CMS-1500, 454, 486
CMS-5010, 486
coagulation testing, 681–682, **682**
code jamming, 486
code mapping, 453
code steering, 486
coding, 445–457
  capitated services, 450
  CPT system, 446–449
  diagnosis, 450–452
  documentation of, 452–453
  procedure, 446, 449
  service location and, 452
coding analyses for labs, 482
coefficient of variation, 265
COLA, 26, 311
collaboration, 86
collecting, 19
collective bargaining, 238
  administration of the agreement, 236
  issues for, 235
  labor actions and disputes, 237
  management rights clause, 236–237, 239
  negotiation phase, 236, **236**
  preparation phase, 235–236
  websites, 240
College of American Pathologists (CAP), 26, 43, 174, 311, 525, 619, 636, 759
  accreditation programs for clinical laboratories, 203
  competency assessment checklist, **195**, 204
  inspection by, 30
  laboratory inspection checklist associated with quality management, 270
  "pathologist pipeline champions," 54
  pathologist pipeline initiative, 54
  Q-Probes program, 254

本书版权归John Wiley & Sons Inc.所有

Q-Tracks program, 254
College of American Pathologists Forensic Drug Testing (CAP-FDT), 249
Collins, Jim, 116, 117
Commission on Office Laboratory Accreditation, *see* COLA
inspection by, 30
commission plans, 563–564, 568
commitment, 102–103
Committee of Three, 705
commoditization, 406
common culture, 84–85
common-source outbreak, 714
communication
acceptance in, 15
ad hoc, 630
attention in, 15
barriers to, 128
channels of, 124
diagonal, 15
downward, 15, 124
effective, 123–133
electronic, 127
emergency management plan, 374–376
empathy in, 15
face-to-face, 130
improving, 131–132
lateral, 15, 124
nonverbal, 128
oral, 125
personal, 630
physician, 555
system developed, 559
telephone, 125
tips to build strong working relationships, **132**
types of, 124–128
upward, 15, 124
visual, 127
written, 125
community-based rating, 87
community-centered testing, 403
comparative effectiveness, 486
compassion, 119
competency, definition of, 194
competency assessment, 204
checklist, **195**
methods, 196–197
personnel excellence, 197
practices, 197
regulatory foundation for, 194
timing of, 194–196
competency-based appraisals, 188
competitive advantage, 85, 406
competitive benchmarking, 619
competitor analysis, 400–401, 406
assumptions, 401
capabilities, 401
goals, 401
interactions, 401
complaint, 238
complete blood counts (CBCs), 677
Complete Guide to Ethics, 20
complex adaptive system, 724
compliance, 492–504
advisory opinions, 502
auditing, 502
coding and billing issues, 498–501
with conflict-of-interest policies, 589–590
fraud alerts, 502
with HIPAA, 588–589
with human subject regulations, 586–588
improper payments, *493*, 493–494
laboratory provider integrity, 497–498
marketing practices, 501–502
medical-necessity issues, 501
monitoring, 502
payor integrity, 497
program integrity, 494–497
record retention, 501
response to possible fraud or abuse, 502–503
special ordering situations, 500–501
compliance program guidance for clinical laboratories, 486
complicated system, 724
composite tests, 487
comprehensive/component edits, 480
computer provider order entry (CPOE) system, 56, 77, 295, 636, 667–668
conditions of coverage (participation), 481–484, 487
confidence interval, 265
conflict
equity, diversity, and inclusion considerations, 148
management, **147**, 147–148
nature of, 144–145
origin of, 145–146
resolution styles, *146*, 146–147
conflict management, 144–149
conflict-of-interest policies
compliance with, 589–590
connectivity, in laboratory information system, 552
consent, 44–45
consent agenda, 138
consolidation, 54–55
definition of, 54
in healthcare industry, 82–84
internal, in hospital laboratories, 83
of practices, 82
constant systematic error, 265
constraints, 409
consultants and consultation, in decision making, 11
consumer, 81
consumer-driven health plan (CDHP), 87
consumer-performed testing, 81
consumer price index (CPI), 470
consumerism, 87
contact tracing, 714
contaminated, 361
contingency theory of management, 7
contingency workforce, 210
continuous lifelong learning, 8
continuous quality improvement (CQI), 8
continuum of care, 563, 568
contract capitation, 69
contractor, 454, 487
contractor advisory committee (CAC), 487
contracts, for outreach programs, 557
contractual allowances, 439
contribution margin, 439
control availability, 337
control limit, 265
control material, 266
controllable costs, 540
controlling, as management function, 15
convener, 136–141
cooperation, in outreach programs, 557
coordination, 697
Core Quality Measures Collaboration (CQMC), 487
copay, 399, 454, 466, 470
coronaviruses, 709
corrosive, 361
cost accounting, 417–437
in benchmarking, 615
break-even analysis, 420
budgeting, 427–430
capital acquisition in, 420–427
financial statements, 434–437
pitfalls in, 507
variance analysis, 430–434
cost-based positioning, 402
cost-based reimbursement, 68
cost-benefit analysis (CBA), 628, 636
cost-effectiveness analysis (CEA), 627–628, 636
cost per billable result, 540
cost per reportable result, 540
cost per test (or cost per result), 540
cost-utility analysis (CUA), 628

本书版权归John Wiley & Sons Inc.所有

cost(s), 17
actual, 418
average, 418
behavior of, 417, *418*
center, 17
classification of, 417
control, 417
in decision making, 529–532, **530**
determining, 468–469
direct, 17, 529
economic, 735
fixed, 440, 529
formula, 418
full, 417–418
indirect, 17, 529
laboratory examples, 419–420
laboratory test, 531–532
marginal, 418
semifixed, 529
standard, 418
unit, 529
variable, 441, 529
cotenancy, 403
Coulter principle, 685
couriers, 561, 565
routes, 567
covered lives, 454
Covey, Steven, 103
COVID-19 pandemic, 709–712, **710**, **711**, 719, 759
definition of, 653
effective mitigative solutions for, 730–731
emergence of, 730
financial challenges created by, 391
laboratory response to, 745–751
management of randomness, 710–711
progressive revelation, 709–710
public response, negotiation of, 711–712
retrospection, 712
special challenges from, 109
subsidence, 712
CPI, *see* Consumer Price Index
CPOE, *see* computerized provider order entry
CPT, *see* Current Procedural Terminology
CPU (central processing unit), 295
CQI, *see* continuous quality improvement
CQMC, *see* Core Quality Measures Collaboration
criteria-based job description (CBJD), 164–167
basic requirements, 164–165, **165**
minimum personnel requirements, 166–167
review, 165–166
criterion, 187
critical incident evaluation, 188
critical pathway, 79
cross-functional teams, 214
cross-training, 413
cross-walking, 454, 470–471
CUA, *see* cost-utility analysis
culture of trust, 85
Cures Act (the 21st Century Cures Act), 57, 283
Current Good Manufacturing Practices (CGMP), 34, 36
Current Procedural Terminology (CPT), 289–290, 295, 330, 446–448, 454, 469, 487, 619
alternatives to, 449
changes in, 448–449, **449**
coding, 499
description, 446
guidance for, 449
modifiers of, 448, **448**
types of, 446–447, **447**
Current Procedural Terminology codes, 698
custom panel, 487
customer relationship management, 295
customer satisfaction, 550–568
assessment, 559–561
cutoff concentration, 249
cytology, 558

D

damage assessment, **377**, 378
DAT, *see* direct access testing
data aggregation, 739
data dashboards, 759
data mining, 619
database, 295
database management system, 295
date of service rule, 485
de Belleville, Nicholas, 315
de Chauliac, Guy, 705
de Gaule, Charles, 100, 102
de Ropp, Robert S., 102
debt management ratios, 439
decentralized testing, 16–17
decertification, 238
requirement, 238
decision making, 9–12, 417
definition of, 10
group, 11
individual, 11
in laboratory outreach management, 528–529
levels of, 532–536, **534**
metrics-based, 536–538
problem-solving in, 11–12, *12*
risk in, 12
time involved in, 12
types of, 10–11
decontamination, 354, **354**, 361
deemed authority, 619
"deemed status," **29**
deep learning, 698
defendant, 61
Deficit Reduction Act of 1984 (DEFRA), 67
DEFRA, *see* Deficit Reduction Act of 1984
DEI (diversity, equity, and inclusion), 148, 162–164, 167
best practices, **164**
delta check, 266, 685
Deming, W. Edwards, 7, 183
denials, 454
Department of Health and Human Services (HHS), 25–26, 117, 478
Department of Justice (DOJ), 489
Department of Transportation (DOT), 42, 356
depreciation, 427, 439, 540, 547
descriptive epidemiology, 714
descriptive statistics, 599, 604
device classification panels, 47
device driver, 295
device miniaturization, 684
DEX Z-codes, 454
DHQ, *see* Donor History Questionnaire
diagnosis coding
ICD-CM, 451–452
inpatient, 450–451
other unique groups, 451
outpatient, 451
SNOMED CT, 452
diagnosis-related groups (DRGs), 17, 18, 67, 454, 464, 487
reimbursement for, 395
diagnostic management teams (DMTs), 60
diagnostic studies, challenges for, 600–601
diagnostic testing, 626
diagonal communication, 15
dictionary, in laboratory information systems, 295
differential or incremental costs, 540
digital scanned slide/microscopy, 196–197
digitalization, 336
Dijulius, John R., 408
direct access testing (DAT), 16–17, 80, 330
pros and cons of, **318**
direct allocation, 439
direct billing, 67
direct consumer access, 80–82
direct costs, 17, 440, 529, 540

本书版权归John Wiley & Sons Inc.所有

direct-to-consumer (DTC) testing
at-home collections, 81
consumer-performed testing, 81
potential risks of, **81**
prescription-required at-home collections, 81–82
direct transmission, 714
directing, as management function, 14–15
disasters
active shooter/hostage response, 380
bomb threat, 380
definition of, 373
external, **376**
fire, 379
hazardous materials, 379–380
internal, **376**
natural, 381
pandemic(s), 381
preparedness, 356
radioactive material, 381
utility failures, 380
discipline-centered testing, 403
discount rate, 440
disinfectant, 361
disinfection, 362
disinformation, 714
Disney, Walt, 584
DMADV acronym, in Six Sigma, 9
DMAIC acronym, in Six Sigma, 9
DMTS, *see* diagnostic management teams
Doctors Company, the, 61
documentation
of codes, 452–453
of employee selection process, 173–174
of performance appraisals, 193
DOJ, *see* Department of Justice
Donor history questionnaire (DHQ), 35
DOT, *see* Department of Transportation
downcode, 454, 487
downtime procedures, 291
downward communication, 15, 124
DRGs, *see* diagnosis-related groups
droplet nuclei, 714
droplet transmission (spread), 714
Drucker, Peter, 164, 182
drug accounts, 565
Drug Amendments of 1962, 26
DTC, *see* direct-to-consumer testing
dues, 238
Dye, Carson, 119

E

EAP, *see* Employee Assistance Program
EBIDTA, 537
EBM, *see* evidence-based medicine
ECL, *see* external contract labor
ECMO, *see* extracorporeal membrane oxygenation
economic costs, 735
economies of scale, 399
economy of scale, 82, 540
education, 203
of ordering providers, 59
EEOC, *see* Equal Employment Opportunity Commission
efficacy, 739
efficiency, in car production, 7–8
effort, 117
EHR-LIS interfaces, 668–670
EHRS, *see* electronic health records
EKRA, *see* Eliminating Kickbacks In Recovery Act
election (NLRB), 238
electrical power, failure of, 380
electronic communication, 126–127
electronic crossmatch, 295
electronic health records (EHRs), 56–59, 295, 649, 660–672, 685
certification, 663–664
components of, 661
computerized provider order entry, 667–668
definition of, 661
formatting incompatibilities, 665–666
information overload, 665
laboratory involvement in selection and implementation, 670–671
laboratory reports, 664–665
module, 672
"order set" challenges, 665
potential consequences, 664
results management, 666–667
status of, 662–663
support staff, tactics for working with, 670
electronic medical records (EMRs), 60, 77, 330, 636
feedback in reports, 631
limits and restrictions on test ordering, 630–631
electronic protected health information (ePHI), 44
Eliminating Kickbacks in Recovery Act (EKRA), 399, 487, 563
elimination, 739
Elizabeth I, Queen of England, 445
email communications, **126**, 126–127, **127**
emergency, 381
emergency management plan (EMP), 374–382
communications, 376–377
damage assessment, **377**, 378
decision to shut down laboratory, 377–378
disasters, 379–382
elements of, **375**
evacuation, **377**, 378
evaluation, **377**, 379
hazard analysis, 373
incident management system, 374–376
locator system, **377**, 378
medical treatment areas, **377**, 378
monitoring, **377**, 379
personnel care, **377**, 378
personnel pool, **377**, 378
policy, 374
purpose, 374
security, **377**, 379
training, **377**, 379
emergency operations center (EOC), 376-379
checklist, 363
Emergency Use Authorization (EUA), 580, 649, 739
emerging infectious diseases, 714
emotional intelligence, 119–120, *120*
EMP, *see* emergency management plan
empathy, in communication, 15
Employee Assistance Program (EAP), 178, 199, 244
employee selection, 161–179; *see also* employee(s) (personnel)
advertising, 167–169
criteria-based job description, 164–167
DEI (diversity, equity, and inclusion) in the workplace, 162–164, **164**
hiring process, 172–174
interview process, 169–172
losing an employee, 175–176
progressive discipline counseling, 176–177
search committee, 167
search process, 167–169
separation from service, 174–178
termination, 177–178, **178**
employee(s) (personnel), *see also* employee selection
accident and exposure report
additional trends and needs of, 111–114
job descriptions for, *see* job descriptions
needs, 108–114
performance appraisal, 190–191
self-empowerment of, 8
employer unfair labor practices, **228**
empowerment at work scale, 111
EMRS, *see* electronic medical records
end-stage renal disease (ESRD), 454, 462, 484, 487, 500, 501

本书版权归John Wiley & Sons Inc.所有

End-Stage Renal Disease Quality Incentive Program (ESRD QIP), 74
endemic, 739
endemic disease, 714
enforcement rule, 45–46
engineering controls, 352, 362
environmental factor, 714
enzyme immunoassay, 249
EOB/EOMB, *see* explanation of (medical) benefit form
EOC, *see* emergency operations center
ePHI, *see* electronic protected health information
epidemic curve, 714
epidemics, 703–716, 739
  of antiquity, 704–709
epidemiological triad, 714
epidemiology, 704
episode of care, 68, 69
EPO, *see* exclusive provider organization
EQC, *see* Equivalent Quality Control
Equal Employment Opportunity Commission (EEOC), **168**, 525
equal opportunity employment regulations, 167, **168**
equipment purchase, 420
equity, 440
Equivalent Quality Control (EQC), 28
Eradication, 739
Ergonomics, 40
  definition of, 40
  general guidelines, 41
error, 266
  log, 295
ESRD, see end-stage renal disease
ESRD QIP, see End-Stage Renal Disease Quality Incentive Program
ethics
  management, 19–20
EUA, see Emergency Use Authorization
evacuation, 377
evaluative listener, 129
evidence-based laboratory medicine (EBLM), 601–603
  clinical decisions through, improving, 78–79
evidence-based measures, 88
evidence-based medicine (EBM), 86, 601, 636, 649
exclusive provider organization (EPO), 70
Executive Order 12564, 242
exit interview, 179
expedited review, for new medical devices, 580
expense budget, 429, 440
experience, decision making and, 11
expert power, 4
explanation of (medical) benefit form (EOB/EOMB), 454, 487
external benchmarking, 619
external communication, 282–283
external contract labor (ECL), 409–410, 414
external disaster, **376**
extinction, 739
extracorporeal membrane oxygenation (ECMO), 685
eye protection, 352

F

face protection, 352
face-to-face communication, 130
face-to-face meeting, 136, **137**
facilitator, 139
facility, 381
FACT, *see* Foundation for the Accreditation of Cellular Therapy
Fair Labor Standards Act of 1938 (FLSA), 228
False Claims Act (FCA), 77
Family and Medical Leave Act (FMLA), 177
faster slide scanning, 678
Fayol, Henri, 4–5
FCA, *see* False Claims Act
FDA, *see* Food and Drug Administration
FDA Safety and Landmark Advancements (FDASLA) Act, 34
FD&C ACT, *see* Food, Drug and Cosmetics Act
FDASLA, *see* FDA Safety and Landmark Advancements Act
feasibility report, 522
Federal Food, Drug, and Cosmetic Act of 1938, 26
Federal Mediation and Conciliation Service (FMCS), 238
Federal Select Agent Program (FSAP), 649
Federal Trade Commission (FTC), 54–55
fee(s), *see* reimbursement
fee-for-service (FFS), 68, 454, 463
  arrangement billing, 466
  discounted payments, 69
fee schedules, 69, 395, 470, 540
FFS, *see* fee-for-service
financial management, 389–395
  basics of, 17–19
  billing, 19
  budgeting, 18
  capital budget, 18–19
  collecting, 19
  costs, 17
  gross *versus* net revenue, 17–18
  managed care, 18
  medicare, 18
  operating budget, 18
  revenue, 17
  revenue cycle, 19
  trends, **20**
financial ratios, 434–437
financial statements, 434–437
fire
  alarm, 379
  confine, 379
  evacuate/extinguish, 379
  rescue, 379
  safety, 359
firewall, 295
FireWire (IEE1394), 295
fiscal year, 440
501(k) approval, 33
501(k) exemption, 33
510(k) and 510(k) review, 578–579
fixed assets, 540
fixed budget, 440
fixed costs, 440, 529, 540, 568
fixed rate, 68
fixed staffing, 204
Fletcher, Walter M., 690
flexibility, 697
flexible budget, 440
flexible staffing, 204, 209
flowchart, 14
FLSA, *see* Fair Labor Standards Act of 1938
fluorescence polarization immunoassay, 249
FMCS, *see* Federal Mediation and Conciliation Service
FMLA, *see* Family and Medical Leave Act
Follett, Mary Parker, 3
Food, Drug and Cosmetics Act (FD&C ACT), 603
Food and Drug Administration (FDA), 330, 487, 525, 575–582, 650, 686, 714, 759
  device databases, **34**
  Emergency Use Authorization (EUA), 580, 649
  establishment registration with, 580
  medical device classification of, 26–27, 576–577
  medical device listing, 580
  postmarket review of, 581
  on process for new devices, 576–580
  in vitro diagnostic tests, 33–34
forced distribution, 189
Ford Motor company, efficiency in, 7
form CMS-1500, 478
formal channels of communication, 124
formal performance appraisals, 184–185, 187–188
  criteria, 187
  job description, 187
  mission statement, 187
  norms, 187–188
  performance standards, 187

本书版权归John Wiley & Sons Inc.所有

Foundation for the Accreditation of Cellular Therapy (FACT), 30–31
Franklin, Benjamin, 271, 744
fraud alerts, 502
"fraud and abuse" provisions, 487, 540
laboratory examples of, 503
response to possible, 502–503
free lunch, 557–558
Freshman, Brenda, 119
FSAP, *see* Federal Select Agent Program, 649
FTC, *see* Federal Trade Commission
FTES, *see* full-time equivalents
full-time equivalents (FTEs), 166, 204, 206, 311, 427, 440, 529, 532, 551, 554, 568, 619, 685
nonproductive, 620
productive, 620
testing, 620
total, 620
full-time workers, 238
fund accounting, 440
future costs, 540
future value (FV), 440
FV, *see* future value

G

GAAPs, *see* generally accepted accounting principles
gainsharing, 224
GAO, *see* General Accountability Office
gap filling, 454, 471
gas chromatography-mass spectrometry (GC-MS), 249
Gaussian distribution, 266
GC, *see* general controls
GC-MS, *see* gas chromatography-mass spectrometry
GCLPs, *see* good clinical laboratory practices
GCPs, *see* good clinical practices guidelines
Gen Z, 162
behaviors, **112**
communication preferences, **113**
cultural preferences and values, **113**
technology styles, **113**
work style, **113**, **163**
workplace strengths, **112**
workplace struggles, **112**
gender-affirming care, 46
gender fluidity, 162, 167
General Accountability Office (GAO), 487
general controls (GC), 33, 47, 576
general ledger, 440
general purpose reagent, 47
generalist, 204–205, **205**
generally accepted accounting principles (GAAPs), 540
Generation X
behaviors, **112**
communication preferences, **113**
cultural preferences and values, **113**
technology styles, **113**
work style, **113**, **163**
workplace strengths, **112**
workplace struggles, **112**
genome, 714
genomics, 78
germicide, 362
giveaways, 557–558
global health security, 724
global surveillance, 735
global teams, 223
gloves, 351–352
GLP, *see* good laboratory practice
GME, *see* graduate medical education
GMPs *see* Good Manufacturing Practices
go-live, 295
goal congruence, 224
goal setting, 224
goals, 117
Goleman, Daniel, 119, 120
good clinical laboratory practices (GCLPs), 592
good clinical practices guidelines (GCPs), 591–592
good faith bargaining, 238
good laboratory practice (GLP), 591–592
Good Manufacturing Practices (GMPs), 580
GPO, *see* group purchasing organization
graduate medical education (GME), 62
graphic rating scales, 188, 189
Graunt, John, 706
Great Resignation, 162
Green Belts, in Six Sigma, 9
grievance, 238
gross billing, 17–18
gross revenue/gross billed revenue, 17–18, 540
group purchasing organization (GPO), 675, 685
group(s)
decisions by, 11
effectiveness, 224
process, *216*, 216–217, 224
growth trap, 405
guidebook, 558, 568

H

HAC, *see* Hospital-Acquired Conditions Reduction Program
halo effect, 191
Hammer, Michael, 84
handwashing, 350–351, **351**
hardware, 286, 288
Harley, Jason, 103
Harrington, H. James, 609
Hawthorne, on productivity, 5
Hawthorne effect, 122
Hazard Communication Standard (HAZCOM), 38
hazardous materials, 378–379
hazards
analysis, 373
biological, 344
chemical, 344–345
classes and definitions, **42**
mental, 346
physical, 346
prevention and containment, 347–354
radiation, 346
HAZCOM, *see* Hazard Communication Standard
hazmat team, 380, 381, 383
HBV, *see* hepatitis B virus
HCC, *see* Hierarchical Condition Category
HCPCS, *see* Healthcare Common Procedure Coding System
Health Care Fraud Prevention and Enforcement Action Team (HEAT), 496
Health Care Service Corporation, 55
health disparities, 55–56
definition of, 55
health informatics, 753–754
health information exchange (HIE), 56
Health Information Technology for Economic and Clinical Health (HITECH) Act, 45, 56, 660, 672
Health Insurance Portability and Accountability Act (HIPAA), 44–47, 77, 283, 288, 322–323, 330, 454, 478, 481, 487, 568, 649
civil violations, tiered penalty system for, **46**
compliance, 46
compliance with, 588–589
criminal penalties, **46**
future of, 644–645
impact of, 644
information blocking rule, 57
laboratory requirements, 644
privacy rule, 45, 57
health maintenance organizations (HMOs), 69–70, **70**, 454
history of, 69–70
health plan, 455, 462
Health Reimbursement Arrangement (HRA), **71**
Health Technology Assessment (HTA), 454–455, 464
Group, 487

本书版权归John Wiley & Sons Inc.所有

Healthcare Common Procedure Coding System (HCPCS), 454, 479–482, 487, 499
Healthcare Effectiveness and Data Information Set (HEDIS), 455, 487
healthcare information systems, 287–288
healthcare personnel, vaccinations and schedule for, 352
healthcare reform, 71–74
HEAT, *see* Health Care Fraud Prevention and Enforcement Action Team
heating, ventilation, and air conditioning (HVAC), 685
HEDIS, *see* Healthcare Effectiveness and Data Information Set
hematology
  cell populations, automated enumeration of, 677–679
  molecular testing, 678
hematopoietic progenitor cells (HPCs), 36
Hemingway, Ernest, 123
hepatitis B vaccination form, 365
hepatitis B virus (HBV), 34, 362, 645
herd immunity, 714–715, 739
Herzberg, Frederick, 118
Hewlett Packard, 282
HIE, *see* health information exchange
Hierarchical Condition Category (HCC), 455
hierarchy, 283
hierarchy of needs (Maslow), 5, 118, 120
high-complexity tests, **28**
high-quality laboratory professionals, 85
high-risk group, 714
high-risk test, 41
Hilbert, Tim, 25
HIPAA, *see* Health Insurance Portability and Accountability Act
Hippocrates, 705
hiring process
  candidate selection, 172–173
  documentation, 173–174
  onboarding, 173
  orientation, 173
historical costs, 540
HITECH, *see* Health Information Technology for Economic and Clinical Health Act
Hittites, 705
HIV/AIDS, 34, 708–709, 713, 714
HL7 (health level 7), 288, 295, 672, 685
HMOs, *see* health maintenance organizations
holidays, 413–414
home draws, 566
home health agencies, 565
home healthcare, 80
honoring your word, 97–99
  current state of, 99
  pitfalls in, 98–99
  trust and relationship to, 99–100
horizontal consolidation, 54
horizontal integration, 54
Hospital Acquired Conditions (HAC) Reduction Program, 75, 455
hospital-based laboratory outreach, 515–526
  administrative interest, 516–518
  business plan, 520–521
  feasibility report, 522
  implementation of, 523
  indicators, 523, **524**
  market, exploring, 518–519
  philosophical understanding, 522
  program, growing, 523–524
  sales plan, 521–522
  service and financial support, 522
  strategic planning, 519–520
hospital-centered testing, 403
hospital environment, 390–393
  financial challenges created by COVID-19 pandemic, 391
  inpatient hospital setting, **391**, 391–393, **392**
  outpatient hospital setting, 393
Hospital Readmission Reduction Program (HRRP), 75
hospital value-based purchasing (VBP) program, 74–75
hospitals
  healthcare reform in, 76
host, 714
HPCs, *see* hematopoietic progenitor cells
HRA, *see* Health Reimbursement Arrangement
HRRP, *see* Hospital Readmission Reduction Program
HSPP, *see* Human Subject Protection Program
HTA, *see* Health Technology Assessment
http (hypertext transfer protocol), 672
hubris, 405
human motivation theory, 121, **121**
  practical issues in resource utilization, 413–414
human profitability, 510
human relations movement, 5
  performance, cardinal rules for optimizing, 410–411
human resource management, 408–415, **409**
  constraints on managerial function, 409, **410**
human resources development, 753
Human Subject Protection Program (HSPP)
  record retention for, 588
  regulatory requirements for, 586
human subject regulations, compliance with, 586–588
  continuing review by IRB, 588
  HSPPs, record retention for, 588
  HSPPs, regulatory requirements for, 586
  informed consent, 587
  risk-based classification, 586–587
  site authorization, 587
  special populations, 587–588
  training requirements, 587
humility, 117
HVAC, *see* heating, ventilation, and air conditioning
hygiene factors, 122
hyperendemic disease, 714

I

IATA, *see* International Air Transport Association
ICD (International Statistical Classification of Diseases and Related Health Problems), 295, 330, 672
ICD-9-CM, *see* International Classification of Diseases, ninth revision (clinical modifications)
ICD-10-PCS, *see* International Classification of Diseases, version 10, procedure coding system
ICD-CM (clinical modification) codes, 451–452, 472, 479, 481, 482, 499–500
IDE, *see* Investigational Device Exemption
identity and vision conflicts, 145
IDN, *see* Integrated Delivery Network
IDS, *see* Integrated Delivery System
image analysis, 525
immature reticulocyte fraction, 685
immunity
  active, 714
  herd, 714–715
  passive, 715
immunization, 352
immunology, 558
immunology-based diagnostics, 729
impasse, 238
imprecision, 266
improper payment, 487
improper payments, *493*, 493–494
imputed costs, 540
in-office phlebotomy, 566
in vitro clinical tests (IVCT), 649
in vitro diagnostic tests, FDA regulation of
  current overview, 33
  laboratory-developed tests, 33–34

本书版权归John Wiley & Sons Inc.所有

in vitro diagnostics (IVD), 330
incidence, 739
incidence rate, 715
incident management system, 374–376
income statements, 440, 507–508
incremental budgeting, 440
incubation period, 715
indemnity plan, *see* Fee-For-Service (FFS)
indirect costs, 17, 440, 529, 540
indirect provider, 649–650
indirect transmission, 715
individual decisions, 11
Individualized Quality Control Plan (IQCP), 28, **29**, 307
inducement, 487
industry analysis, 525
infant mortality, 55
infection surveillance, 759
infectious agents
  CDC/NIH-recommended biosafety levels for, **347**
infectious hazards, 39–40
infectious substances
  classification of, 357–358
  packaging of, 358–359
  shipping of, **358**, 358–359
infectious waste, 362
infectivity, 715
inferential statistics, 599–600, 604
inflation, 540
influenza, 707–708
infodemic, 715
informal channels of communication, 124
informal performance appraisals, 184–185
informatics, 692–693
informatics, laboratory's role in, 78
information blocking rule, 57
information review, 339–340
information technology (IT), 759
  role in hospitals, 59
informed consent, 587
inherent reasonableness, 455
inpatient hospital setting, **391**, 391–393, **392**
inpatient payment classifications, 484
INR, *see* International Normalized Ratio
Institute of Medicine (IOM), 455, 650
institution-based approaches to control
  formal protocols, validation of, 632
  major events, 633
  test formulary, 632–633
  working with providers, 631–632
institutional profitability, 509–510
instrument interface, 290
Integrated Delivery Network (IDN), *see* Integrated Delivery System (IDS)
Integrated Delivery System (IDS), 82
Integrated Service Network (ISN), 70
integrated theory of management, 6–9
integrity, 97–100
  definition of, 97
intellectual property, 590
intelligence, 724
  emotional, 119–120, *120*
interaction process, 131–132
interdepartmental communication, 282
interest rate, 440
interface, 295, 672, 685
interface engine, 296, 672
interference, 266
internal benchmarking, 611, 619
internal disaster, **376**
internal rate of return (IRR), 440
Internal Review Board (IRB), 650
International Air Transport Association (IATA), 42, 362
International Classification of Diseases, clinical modification, 455, 487
International Classification of Diseases, ninth revision (clinical modifications) (ICD-9-CM), 525
International Classification of Diseases, version 10, Procedure Coding System (ICD-10-PCS), 455, 487
international normalized ratio (INR), 685
International Organization for Standardization (ISO), 271–277
  background, 271–272
  certification *versus* accreditation, 272
  ISO 9001, 272–274
  ISO 15189, 274–277
internet, 296
interoperability, 672
interpersonal issues, intrusion of, 412
interspecies and intergenerational health equity, 724
interventional diagnostics, 604
interview process
  "do's and don'ts," 171–172
  formats, 170
  performance appraisal, 191–192
  questions, 170–171
  résumés, screening, 169–170
  tips, **171**
intradepartmental communication, 281–282
intranet, 296
intuitive decisions, 11
invasive species, 724
Investigational Device Exemption (IDE), 47
invoice billing, 465
IOM, *see* Institute of Medicine
IP (Internet Protocol) address, 287, 296
IQCP, *see* Individualized Quality Control Plan
IRB, *see* Internal Review Board
IRR, *see* Internal Rate of Return
ISBT 128, 296
Isgar, Thomas, 144
ISN, *see* Integrated Service Network
ISO 9001
  ISO 15189 *versus*, 275
  principles of, 272–273
  standards related to, 273–274
ISO 15189
  accreditation, 275–277
  CLIA '88 and, 275
  documents related to, 275
  ISO 9001 *versus*, 275
  laboratory management team, considerations for, 275–276
  principles of, 274–275
  structure of, 274
IT, *see* information technology
IVCT, *see in vitro* clinical tests
IVD, *see in vitro* diagnostics

J

Jenner, Edward, 706
job descriptions, 15
job enrichment, 116
job order costing, 540
job postings
  words and phrases to avoid in **168**
JSON (JavaScript Object Notation), 672
judgmental decisions, 11

K

510(k) clearance, 27
Kanban, 84
Kennedy, Robert F., 97
key expense indicators, 508–509
key income indicators, 508
key results area, 188
kickback, 488
kinetic microparticle immunoassay, 249
King, Martin Luther, Jr., 652
Kinyoun, Joseph J., 706
Kitasato, Shibasaburo, 706
knowing yourself, 100–101
knowledge of self, 117–118
Koch, Robert, 707
Kotter, John, 153
Kotter model of change management, 153

本书版权归John Wiley & Sons Inc.所有

KSAs (knowledge, skills, and abilities), 217–218
interpersonal, **217**
staff management, **217**
teamwork test, **218**
Kurec, Anthony, 25

L

LabCorp, 16
labor law, 226–230, **228**
Labor-Management Relations Act of 1947 (Taft-Hartley Act), 228, **229**
Labor-Management Reporting and Disclosure Act of 1959 (Landrum-Griffin Act), 229
labor relations, 226–238, *227*
labor shortage, 202–203
laboratory, 383
Laboratory Accreditation Program (LAP), 194
Laboratory Benefit Management Program (LBMP), 455
laboratory-developed tests (LDTs), 33–34, 330, 455, 488, 650
laboratory information system (LIS), 119, 285–297, 636, 672, **676**, 685
administration, 290–291
architecture, 288–289
cloud computing, 287
dictionary, 672
hardware, 286
healthcare information systems, 287–288
interfaces, 289–290
networking, 287
selection and implementation, **292**, 292–293
software, 286–287
specialty considerations, 293–294
validation, 291
laboratory management, *see also* management functions; management theory; manager(s)
communicating to diverse audiences, 280
effective communication in, 278–283
external communication, 282–283
formal proposal to change laboratory services, **282**
interdepartmental communication, 282
intradepartmental communication, 281–282
means and mechanics, 280–283
message, 279–280, **280**
off shifts, 551
spoken word, 281
written word, 281
Laboratory Management Index Program (LMIP), 206
laboratory managers
decision making by, 9–12
problem solving by, 11–12
laboratory medicine, 698
future practice of, 690–698
regulatory issues in, 25–48
Laboratory Medicine Best Practices (LMBP), 604
laboratory networks, 756–757
laboratory preparedness, 744–760
appropriate outbreak testing, 750
distribution, 751–752
executive plan, 752–753
framework for, 751–756
future directions, 757–758
healthcare and laboratory systems, organization of, 748
heath informatics, 753–754
human resources development, 753
impediments to, **746–747**
implementing new tests and surge capacity, 748–750
manufacturing, 751–752
mHealth, 754–756
new outbreak tests, implementation of, **749**
quality, 750–751
regulatory requirements, 751
specimen logistics and transportation, 754
staffing, 750–751
supply chains, 750
laboratory provider integrity, 497–498
laboratory reimbursement regulation
U.S. healthcare, 42–44
laboratory safety, 343–362, 350–351
audit, *360–361*
barrier protection, 351–352
biological hazards, 344
biological safety cabinets, 353
biosafety level criteria, **348**
chemical fume hoods, 353
chemical hazards, 344–345
decontamination, 354, **354**
disaster preparedness, 356
engineering controls, 352
fire safety, 356
handwashing, 350–351, **351**
immunization, 352
infectious substances, *see* infectious substances
mental hazards, 346
personnel training, 359
physical hazards, 346
radiation hazards, 346
respiratory protection, 352
risk assessment, 347–350, **348–350**
safety management plan, 344, *344*
spill management, 355–356
standard precautions, 346–347
sterilization, 354, **354**
warning signs and labels, 353
waste management, 356–357
work practices, 352
laboratory services organization (LSO), 70
laboratory supervisor, 210
laboratory test cost, 531–532
laboratory test formulary, 59–60, 672
laboratory tests and testing
POCT, *see* point-of-care testing (POCT)
in vitro diagnostic tests, FDA regulation of, 33–34
laboratory(ies)
as business, 527–528
centralization of, 16
consultation, 695–696
decision to shut down, 377–378
"deemed status," **29**
demographics of, **390**
design, 84
exempt from CLIA '88, 31
formularies and utilization committees, 59–60
healthcare reform in, 76–77
inspection, 29–33
location, 204
management of, *see* management functions; management theory; manager(s)
organizational chart, 24
regulatory environment, **27**
requirements, defining, 334–335, **335**
responsibilities, 46–47
role in patient care and public health response, **745**
role in informatics, 78
roles of, 712–713
service levels, 204
size, 204
strategic plan, 23
test menus, 204
utilization, 58–60, 698
value, 510–511
LAMP, *see* loop-mediated isothermal amplification
LAN, *see* local area network
landscape, 724
LAP, *see* Laboratory Accreditation Program
large-scale clinical trials, 597
latency period, 715
lateral communication, 15, 124

本书版权归John Wiley & Sons Inc.所有

lateral-flow immunoassay, 685
latex, regulatory requirements, 40–41
latex allergy, 362
LBMP, *see* Laboratory Benefit Management Program
LC -MS, *see* liquid chromatography-mass spectrometry
LCDs, *see* local coverage determinations
LDTs, *see* laboratory-developed tests
leader(s), 4; *see also* leadership
  definition of, 4
  versus managers, 4
leadership, 95–105
  as conduit of motivation, 117
  decision making in, 9–12
  definition of, 95–96
  hospital, 60
  legitimacy, 224
  in team environment, 219–220
  versus management, 3–4, 95–97, **96**
lean processing, 685
lean Six Sigma, 9
learning, continuous lifelong, 8
lease, 540
left ventricular assist device (LVAD), 685
level 1 leadership, 122
level 2 leadership, 122
level 3 leadership, 122
level 4 leadership, 122
level 5 leadership, 122
Lewin, Kurt, 152
LGBTQIA+ community, 55, 56
liabilities (and liability accounts), 440
liability (legal), future decisions on, 645
licensing and licensure
  personnel, 31–33
  states requiring, 33
life cycle management, 8
  total product, 8
Lifshitz, Mark S., 25
linear programming models, 6
liquid chromatography–mass spectrometry, 249
liquidity ratio, 440
LIS, *see* laboratory information system
list price, 540
listening
  effective, 128–129
  ineffective, 129
  stages of, 129
  types of, 129
livestock, 724
LMBP, *see* Laboratory Medicine Best Practices
LMIP, *see* Laboratory Management Index Program
LMRPs, *see* Local Medical Review Policies
load balancing, 296
local area network (LAN), 287, 296
local coverage determinations (LCDs), 481, 488, 497
local coverage policies, 556
Local Medical Review Policies (LMRPs), 516, 525–526
locator system, **377**, 378
lockout, 238
Logical Observation Identifier Names and Codes (LOINC), 330, 455, 672, 685
LOINC, *see* Logical Observation Identifier Names and Codes
long-term debt, 440
loop-mediated isothermal amplification (LAMP), 685
loss leader, 540
Lowry, A. C., 147
loyalty-based management, 85
LSO, *see* Laboratory Services Organization
LVAD, *see* left ventricular assist device

M

MA, *see* Medicare Advantage
machine learning (ML), 603, 604, 693
MACRA, *see* Medicare Access and Chip Reauthorization Act of 2015
macrocost analysis, 303, 311
MACs, *see* Medicare Administrative Contractors
MAE, *see* maximum allowable error
Malaguzzi, Loris, 202
MALDI, *see* matrix-assisted laser desorption ionization
malpractice
  in the age of COVID-19, 61
  pre-COVID-19, 60–61
manageable components, 415
managed care, 69, 455
  effect on clinical laboratories, 71
managed care organizations (MCOs), 18, 82
  types of, 69–71
management, 3–22; *see also* laboratory management; leadership; management functions
  versus administration, 3–4
  decision making in, 9–12
  definition of, 96
  ethics, 19–20
  emergency, 374–382
  history of, 4–9
  human resource, 408–415
  versus leadership, 3–4, 95–97, **96**
  reporting, 440
  science, 6
  teams, 213
  theories of, 4–9
management by objectives (MBO), 6, 8, 21
"management by walking about" (MBWA), 282–283
management functions, 12–16
  controlling, 15
  directing, 14–15
  organizing, 14
  planning, 12–14
management rights clause, 236–237, 239
management services organization (MSO), 71
management theory, 4–9
  behavioral, 5–6
  classical, 4–5
  emergence of, **9**
  integrated, 6–9
  quantitative, 6
managerial "employee," 239
managerial function, constraints on, 409, **410**
manager(s), *see also* laboratory managers
  decision making, 9–12
  as problem solvers, 11–12
  risk taking by, 12
  systems-oriented, 7
  versus leaders, 4
Mandatory Guidelines for Workplace Drug Testing Programs, 243
Manufacturer and User Facility Device Experience (MAUDE), 33
marginal costs, 418, 440, 540
marginal listener, 129
markets and marketing, 518–519, 526
  ordering provider and patient communication, 502
  in outreach programs, 559
  pricing and inducements, 501–502
  professional, 563–564
  segment, 526
Maslach Burnout Inventory, 109
Maslow, Abraham, hierarchy of needs, 5, 118, 120
Mass, Diana, 161
master patient index (MPI), 287, 296
material safety data sheet (MSDS), 362
mathematical models, for efficiency, 6
matrix, 266
matrix-assisted laser desorption ionization (MALDI), 685
MAUDE, *see* Manufacturer and User Facility Device Experience
maximum allowable error (MAE)
  specification of, 259–260, **260**, 266
Mayo, Elton, 5

本书版权归John Wiley & Sons Inc.所有

MBO (management by objectives), 6
MBWA, *see* "management by walking about"
MCAC, *see* Medical Contractor Advisory Committee
McClelland, David, 121, **121**
McGregor, Douglas, 5
MCOS, *see* managed care organizations
mean, 266
meaningful-use criteria, 662, 663, 672
mechanistic studies, 596
MEDCAC, *see* Medicare Evidence Development and Coverage Advisory Committee
Medicaid, 42–43, 239, 455, 488
Medicaid Integrity Contractors (MIC), 496
Medical Contractor Advisory Committee (MCAC), 482
Medical Device Amendments of 1976, 27
Medical Laboratory Science (MLS), 53, 85
Medical Laboratory Technology (MLT), 53, 85
medical necessity, 455, 481, 488, 501, 568
medical review officer (MRO), 249
medical scribe, 62
medical technician, 210
medical technologist, 210
medical technologists, increasing opportunities for, 203
medical training, climate of, 61
medical usefulness limits, 266
medically unlikely edits (MUEs), 480–481, 488
Medicare, 18, 42, 43, 239, 455, 488
  claims processing, 43
  laboratory test reimbursement, 44
  Part A, 18, 455, 478
  Part B, 455, 478
  Part C, 455
  pathology and laboratory services in, 43
  physician services, reimbursement for, 43–44
Medicare A/B contractor, 455
Medicare Access and Chip Reauthorization Act of 2015 (MACRA), 43, 54, 74, 619
Medicare Administrative Contractors (MACs), 43
Medicare Advantage (MA), 462
Medicare coverage database, 482
Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), 482
Medicare Prescription Drug, Improvement and Modernization Act of 2003 of 2003 (MMA), 455, 462
Medicare Secondary Payor (MSP), 526, 568
  questionnaires, 555
Medicare Shared Savings Program (MSSP), 74
medicolegal issues
  malpractice in the age of COVID-19, 61
  malpractice pre-COVID-19, 60–61
meetings
  agenda, 137–138
  communication in, 130, **130**
  cost of, 141
  effective, 135–142
  minutes, 140
  need for, 136
  organization of, 139–140
  participants, 139, 141
  reasons to hold, 136
  recurrent, 141
  technology/equipment required for, 139
  troubleshooting, **142**
  types of, 136–137, **137**
  venue of, 139
memos, writing guide for, **125**
men who have sex with men (MSM), 35, 60
mental hazards, 346
mentor, benefits of becoming, 192
mergers and acquisitions, 54, 82
Merit-Based Incentive Payment System (MIPS), 43–44, 74, 75, 619, 650
MERS, *see* Middle East respiratory syndrome
MERS-CoV, 715
meta-analysis, 597, 604
metagenomics, 739
mHealth, 754–756
miasma theory, 715
MIC, *see* Medicaid Integrity Contractors
microbiology, 293
  advances in, 680
  automated instruments, **681**
  microorganism identification, 681
  molecular, 681
microbiome, 739
microcost analysis, 311
microcosting, 531, 540, 543–546
microexpressions, 128
microorganisms
  identification of, 681
  WHO classification of microorganisms, **347**
Middle Class Tax Relief and Job Creation Act of 2012, 75
Middle East respiratory syndrome (MERS), 709, 715
middleware, 296
millennials
  behaviors, **112**
  communication preferences, **113**
  cultural preferences and values, **113**
  technology styles, **113**
  work style, **113**, **163**
  workplace strengths, **112**
  workplace struggles, **112**
Mims, Christopher, 119
minor chemical spill cleanup procedure, 367
minutes, 140
MIPS, *see* Merit-Based Incentive Payment System
misinformation, 715
mission statements, 13
  formal performance appraisals, 187
mixed costs, 540
ML, *see* machine learning
MLS, *see* Medical Laboratory Sciences
MLT, *see* Medical Laboratory Technology
MMA, *see* Medicare Prescription Drug, Improvement and Modernization Act of 2003
mobile laboratory service, 759
mode of transmission, 739
Model Laboratory Compliance Program, 568
moderate-complexity tests, **28**
modifier, 448, **448**, 455, 488, 499
MolDx, 455–456
molecular diagnostics, 294, 683, **683**
molecular microbiology, 681
molecular test panel, 685
molecular testing, 57–58, 678
monitoring devices, 311
monthly call review, 571
moral mazes, 20
morbidity, 715, 739
mortality, 739
  rate, 715
motherboard, 296
motivation
  definition of, 116, 121
  factors of, 118
  self-motivation, 120
  theory of, 5
  through intelligent leadership, 116–122
motivators, 121
MPI, *see* Master Patient Index
MRO, *see* Medical Review Officer
MSDS, *see* Material Safety Data Sheet
MSM, *see* men who have sex with men
MSO, *see* management services organization
MSP, *see* Medicare secondary payor
MSSP, *see* Medicare Shared Savings Program
MUEs, *see* medically unlikely edits
multi-hospital core laboratory, 403
multiple pathology groups, 558
Murrow, Edward R., 278

本书版权归John Wiley & Sons Inc.所有

Murthy, Narayana, 97
mutually exclusive codes, 480

N

N of a disease, 715
narrative rating, 188
National Accrediting Agency for Clinical Laboratory Sciences, 31
National Center for Health Statistics (NCHS), 55
National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 586
National Committee for Clinical Laboratory Standards (NCCLS), 203
National Correct Coding Initiative (NCCI), 456, 479–480, 488, 493
National Coverage Decision (NCD), 526
national coverage determinations (NCDs), 481–482, **482**, 488
national coverage policies, 482, 556
National Credentialing Agency (NCA), 33, 203, 204
National Healthcare Safety Network (NHSN), 456, 488
National Hospital Association, 53
National Institute for Occupational Safety and Health (NIOSH), 41
National Institutes of Health (NIH), 715
  on health disparities, 55
  on mental health, 163
National Labor Relations Act (NLRA) of 1935, 228
  employer unfair labor practices, **228**
  1974 amendments to, 229–230
  notice requirements, **229**
  union unfair labor practices, **229**
National Labor Relations Board (NLRB), 228
  authority to secure injunctive relief from a court, 230–231
  description, 230
  function, 230
  issues related to, 231
  processing of cases, 230
  structure, 230
national limitation amount (NLA), 456, 499
National Medical Laboratory Professionals Week, 118
national provider identifier (NPI), 488
National Research Act of 1974, 586
National Uniform Billing Committee of the American Hospital Association, 452, 478
natural disasters, 356, 377, 380
NCA, *see* National Credentialing Agency
NCCI, *see* National Correct Coding Initiative
NCCLS, *see* National Committee for Clinical Laboratory Standards
NCD, *see* National Coverage Decision; national coverage determinations
NCHS, *see* National Center for Health Statistics
needs
  assessment, 296
  business, 203
  client, 524
  hierarchy of, 5, 118, 120
  for purpose, 120–121
needs-based positioning, 402
"Neg Reg," 456, 488
negative language, 131
negative predictive value, 330
neglected tropical diseases (NTDs), 712, 715
net contribution margin, 540
net present value (NPV), 440, 541
net profit, 541
net revenue, 17–18, 541
network interface controllers (NICs), 287, 296
networking, 287
neurodiversity, 163
neutralizing antibody, 715
new equipment and procedures
  implementation, 340
  personnel competency assessment and training, 341
  product placement, 340
  proficiency testing, 341
  validation, 340–341
  verification, 340
new equipment and procedures, selection and implementation of, 333–342
  confidentiality, 339
  conflict of interest, 339
  financial, 338
  human resources, 337–338
  information review, 339–340
  physical and technology requirements, 337
  prioritization of requirements, 338–339
  technical/performance considerations, 335–337
newsletter, 559, 629–630
next-generation sequencing (NGS), 685
NGS, *see* next-generation sequencing
NHSN, *see* National Healthcare Safety Network
NICs, *see* network interface controllers
NIH, *see* National Institutes of Health
NIOSH, *see* National Institute for Occupational Safety and Health
NLA, *see* National Limitation Amount
NLRA, *see* National Labor Relations Act of 1935
NLRB, *see* National Labor Relations Board
no-solicitation rule, 239
no-strike, no-lockout clause, 239
"No Surprises" Act, 456, 647
non-hospital environment, 393–394
non-staff physicians, 552
noncontrollable costs, 541
noncovered services, 69
nonlistener, 129
nonproductive FTE, 620
nonproductive time, 440
nonprogrammed decisions, 11
nonstaff physicians, 568
nonverbal barriers to communication, 128
nonverbal communication, 128
normal range, 266
norms, 188–189
Norris-Laguardia Act of 1932, 226
nosocomial, 715
nowcasting, 739
NPI, *see* national provider identifier
NPV, *see* net present value
NTDs, *see* neglected tropical diseases
nursing homes, 564–565

O

OAuth (open authentication), 672
OBRA, *see* Omnibus Reconciliation Act of 1989
observational studies, 596
occupational exposure, 362
Occupational Safety and Health Administration (OSHA), 36–38, 526, 650
  bloodborne pathogen standard, 38
  comprehensive plan to reduce ergonomic injuries, 40
  "enforcement procedures for the occupational exposure to bloodborne pathogens," 38
  Office of Ergonomics Support, 40
  standards for occupational exposure to blood-borne pathogens, 645
OCR, *see* Office of Civil Rights
Office of Civil Rights (OCR), 45
Office of Research and Contract Analysis (ORCA), 585–586
office of sponsored projects (OSP), 585
Office of Inspector General (OIG), 57, 473, 488, 526
  compliance program guidance for clinical laboratories, 497, 498
Office of the National Coordinator for Health Information Technology (ONC), 57, 672
OIG, *see* Office of Inspector General
Oldenburg Burnout Inventory, 109

本书版权归John Wiley & Sons Inc.所有

Omnibus Reconciliation Act of 1989 (OBRA), 67
omnibus rule, 45
onboarding, 173
ONC, *see* Office of the National Coordinator for Health Information Technology
One Health, 717–724
  confronting the reality of complexity, 722–723
  definition of, 718–719
  intelligence, 719–721
  operational impediment and opportunities, 721–722
  and pandemic risk management, 719–721
online presentations, 125–126, **126**
operating budget, 18, 427–429, 440
operating lease, 541
operating status report form, 385
operating system, 296
operational assessment, 526
operational efficiency, 396–397
operational throughput, 336
operations management, 6–9
OPIM, *see* other potentially infectious material
opportunity costs, 541
oral communication, 125
orders interface, 289–290
organization conflicts, 145
organizational changes, 550–551
organizational chart, 14
organizational climate, 85, 130–131
organizational theory of management, 5
organizing, as management function, 14
orientation, 173
  program checklist, **174**
OSHA, *see* Occupational Safety and Health Administration
Osler, William, 703
other potentially infectious material (OPIM), 362
out-of-pocket costs, 541
outbreak, 715, 759
outcome, 69
  assessment, 488
outlier verdict, 60
outpatient-centered testing, 402
outpatient hospital setting, 393
outreach programs
  acceptance of payors in, 554
  accounting in, 552–553
  capital funding for, 553
  centralized operations in, 551
  communication in, 558–559
  contracting in, 554
  failure to understand financial implications and requirements, 554
  full-time equivalents in, 554
  high-profile treatment of, 551
  hospital systems *versus* separate systems, 551–552
  hospital's point of view of, 554–555
  information technology for, 551–553
  insurance plans, 554
  patient registration in, 552–553
  physician office connectivity in, 553
  populating patient record in, 553
  translating hospital and laboratory compliance for, 555–558
outsourcing, 208
overhead costs, 440
overperforming employee, 412
overtime, 414
owners' equity, 440

P

paid hours, 620
PAMA, *see* Protecting Access to Medicare Act of 2014
pandemic fatigue, 729, 740
pandemic mitigation, *738*
pandemic planning, 727–740, *731*
  challenges facing clinical and public health laboratories, 732–734
  early recognition, 729–730
  future partnerships, 734–738
  investments in novel therapeutics, 728
  organization chart, *737*
  paradigm shift, 731–732
  progression in understanding the evolution, 728–729
  role for immunology-based diagnostics, 729
pandemic preparedness, 724
pandemic vulnerability intelligence, 720–721
pandemic(s), 380, 715, 739, 759
  in Anthropocene, 718
Panteghini, Mauro, 626
Pap mills, 26
parallel teams, 213
parenteral, 362
Pareto principle (80/20 rule), 330
part-time workers, 239
partial thromboplastin time (PTT), 685
participation, in outreach programs, 557
participative selection, 224
Pasteur, Louis, 727
path of workflow, 330
pathognomonic, 724
pathologist shortage, 86
pathology
  bioinformatics, impact of, 79–80
  informatics, 78
  pipeline, 54
  telepathology, 80
patient, 541
Patient-Centered Laboratory Utilization Guidance Services (PLUGS), 330
patient informed rights, 44
patient-oriented research (POR), 595, 604
  confounding variables and bias, 598
  data analysis, 599
  data collection, 598–599
  data storage, 598–599
  endpoints, 598
  feasibility, 598
  human subject protection, 598
  hypothesis generation, 598
  measurements, 598
  sample size, 598
  sampling the population, 598
  study design, 597
Patient Protection and Affordable Care Act of 2010 (PPACA), 71–74
  implementation timeline, **71–73**
Patient Safety and Adverse Events Composite (CMS PSI 90), 75
patient safety movement, 646
"pay and chase," 488
"pay it right," 488
payback method, 547
payback period, 541
Payment Error Rate Measurement (PERM), 496
payment reform, 74–77
payor, definition, 68
payor integrity
  postpayment review, 497
  prepayment review, 497
payor mix, 456, 462–464, 541
PBSCs, *see* peripheral blood stem cells
PCR, *see* polymerase chain reaction
pecking order, 145–146
peer-to-peer appraisals, 190
PEL, *see* permissible exposure limit
Penney, James Cash, 515
per diem, 68, 395
per-member-per-month fee (PMPM), 17, 68, 69, 541
performance, cardinal rules for optimizing, 410–411
performance appraisals, 15, 182–194
  advantages of, 183–184
  appropriate behaviors, strategies to reinforce, 192

本书版权归John Wiley & Sons Inc.所有

assumptions, **185**
competency-based appraisals, 188
definition of, 182–183
disadvantages of, 183
documentation, 193
do's and don'ts of, **191**
emotional outbursts during, 193
formal, 184–185, 187–188
history of, 183
improvement plan, 193
informal, 184–185
interview, 191–192
mentors, 192
peer-to-peer appraisals, 190
poor performers, guidelines for appraising, 192–193
preappraisal preparation, 190–191
program, legal aspects of, 186
purpose of, 183
rating methods, 188–189, **189**
responsibility for developing, 186
salary adjustments, 192
self-appraisal, 189–190
360-degree evaluations, 190
trends of, 184
web-based software products, 193–194, 201
websites, 193–194, 201
performance monitoring, 613–616
performance standards, 187
Pericles, 705
period costs, 541
perioperative care, 685
peripheral blood stem cells (PBSCs), 36
peripheral devices, 296
PERM, *see* Payment Error Rate Measurement
permissible exposure limit (PEL), 362
personal communication, 630
personal protective equipment (PPE), 58, 362
personalized medicine, 76
personnel care, **377**, 378
personnel pool, **377**, 378
PFS, *see* Physician Fee Schedule
Phelps, Michael, 298
PHI, *see* protected health information
PHO, *see* physician hospital organization
physical barriers to communication, 128
physical hazards, 40–41, 346
physicial well-being, 61
physician acknowledgments, 555
physician communication, 555
physician fee schedule (PFS), 75, 456, 471
physician hospital organization (PHO), 71
physician office connectivity (POC), 553, 568
physician office laboratory (POL), 30, 456
Physician Quality Reporting System (PQRS), 650
Physician Self-Referral Law (Stark Law), 67, 77, 456, 489, 526, 643, 650
Pickett, R.B., on leadership, 10
pitchfork effect, 191
plaintiff, 60
planning
as management function, 12–14
strategic, 12
SWOT analysis in, 13
plaque, 705–706
platelet measurements, 678
Plebani, Mario, 626
PLUGS, *see* Patient-Centered Laboratory Utilization Guidance Services
PMA, *see* premarket approval
PMPM, *see* per-member-per-month fee
POC, *see* physician office connectivity
POCT, *see* point-of-care testing
point-of-care testing (POCT), 19, 77, 79–80, 117, 294, 678–679, 698, 759
accreditation, 300
administrative considerations, 299–300
advantages and disadvantages of, **79**, **302**
analytical processes, 306–307
benefits of, 304–306
centralized, 16
clinical outcomes, 305–306
computerization, 682
cost analysis, 302–304
decentralized, 16, 17
developments during COVID-19, 682, **682**
goal of, 300, **300**
and home healthcare, 80
improved access to healthcare, 305
innovation, 309–310
key performance indicators, 308–309
laboratory certification, 300
length of stay, 304
management of, 298–311, **299**
management structures, development of, 301
new monitoring technologies, 310
operational management of, 301–309
organizational management of, 299–301
postanalytical processes, 307–308
preanalytical processes, 306
quality management, 306–309
rapid assays, 682
resource utilization, 304
scope of, 301–302
stewardship, 304
technological management of, 309–310
weighing *versus* alternatives, 302
point of service (POS), 71, 456
POL, *see* physician office laboratory
policies, 14
policy changes, 630
polymerase chain reaction (PCR), 294, 715, 740
population health, 724
POR, *see* patient-oriented research
POS, *see* point of service
positive language, 131
positive patient identification (PPID), 289, 296
positive predictive value, 330
postanalytic activities
report, **325**, 325–326
reports, *327*
retention, 326–329, **328**
storage, 326–329
postpay audits, 488
power, 121
PowerPoint presentation, 125–126, **126**
PPACA, *see* Patient Protection and Affordable Care Act of 2010
PPE, *see* personal protective equipment
PPID, *see* positive patient identification (PPID)
PPMPs, *see* provider-performed microscopy procedures
PPOs, *see* preferred provider organizations
PPSs, *see* prospective payment systems
PQRS, *see* Physician Quality Reporting System
"pre-submission (Q-sub)" process, 579
preanalytic activities, 316–325
advance beneficiary notice, 325
appropriateness, 321–322
communication, 322–323
cost studies, 319–320
electronic test requests, 324
factors affecting, **319**
predictive values, 318–319
problem identification and resolution, mechanisms for, 323–324
requisition information, 323
specimen transfer to reference laboratory, 323
test complexity, 316–317
test evaluation, 321
test nomenclature, 318
test ordering, 324–325
test reimbursement, 319
test requisition, **324**, 324–325
test sensitivity, 318–319
test specificity, 318–319
test utilization, 321–322
types of tests, **317**, 317–318

本书版权归John Wiley & Sons Inc.所有

preanalytic activities (*cont'd*)
validation, 320–321
verification, 320–321
predatory pricing, 541
preferred provider organizations (PPOs), 70, 456
premarket approval (PMA), 26, 33, 330
of new medical devices, 577–578
premarket notification, 47
review, of new medical devices, 578–579
PREP ACT, *see* Public Readiness and Emergency Preparation Act of 2005
prepackaged information, 564
prepay edits, 488
present value (PV), 440, 541, 548
preterm birth, 55
prevalence, 715, 740
prevalence rate, 715
prices and pricing, *see also* fee schedules
for outreach programs, 556
transparency regulations, 456
in variance analysis, 440
primary container, 362
prions, 362
prior authorization, 456, 488
prioritization, in benchmarking, 612
priority pathogens list (who), 760
privacy protection, 760
privacy rule, 45
problem solving
decision making in, 11–12
teams, 213
procedure coding, 446
alternatives to, 449
guidance for, 449
procedure/protocol, 330
procedure-to-procedure edits (PTP), 488
procedure(s), 14
process, 330
process costing, 541
process loss (gain), 224
process reengineering, 8–9
product code classification database, **34**
product differentiation–based positioning, 402–403
product offering, 566
product placement, 340
production, lean, 9
productive FTE, 620
productive time, 440
productivity
measures, 207
work environment and, 5
professional employees, 239
professional marketing, 563–564
professional services, 558
proficiency testing, **262**, 262–263, *263*, 341
profit, 488
profit and loss, 541
profitability
analysis, 417
determination of, 506–511
human, 510
institutional, 509–510
key indicators, 508–509
laboratory, 507–508
laboratory value, **510**, 510–511, **511**
pitfalls in cost accounting, 507
ratios, 440, 488
trap, 405
program integrity, 488
activities in, 495–497, **496**
authority for, 494–495
programmed decisions, 10–11
progressive discipline counseling, 176–177
project teams, 213
proportional systematic error, 266
prospective payment systems (PPSs), 68, 456, 472
protected health information (PHI), 288, 650
definition of, 44
electronic, 44
Protecting Access to Medicare Act of 2014 (PAMA), 44, 76, 456, 470, 471, 479, 488, 499, 557, 568
protective clothing, 352
proteomics, 79, 740
prothrombin time (PT), 685
provider documents, 486
provider mix, 456, 461
provider-performed microscopy, 311, 395
provider-performed microscopy procedures (PPMPs), 28, 29
psychological barriers to communication, 128
PT, *see* prothrombin time
PTP *see* procedure-to-procedure edits
PTT, *see* partial thromboplastin time
public health, 760
public-health surveillance, 715
Public Readiness and Emergency Preparation Act of 2005 (PREP Act), 61
pull-through, 568
pulse oximetry, 565–566
purchase, 549
purchaser, 74, 82
purchasing and contracting consortia, 403–404
purpose, need for, 120–121
PV, *see* present value

Q

Q-Probes program, 254, 636
Q-Tracks program, 254, 636–637
QA, *see* quality assurance
QAO, *see* quality assurance office
QC, *see* quality control
QI, *see* quality improvement
QMS, *see* quality management system
QPP, *see* Quality Payment Program
QSRs, *see* quality system regulations
quality
circles, 214
in decision making, 11
quality assurance (QA), 266, 283, 620, 637
quality assurance office (QAO), 591
quality control (QC), 28, 258
CLIA, 28
external (proficiency testing), **262**, 262–263, *263*
frequency of analysis, 258, **259**
rules, 258, **259**
quality improvement (QI), 620
quality management, 253–266
of analytical processes, **257**, 257–263
corrected and incomplete reports, 264
document control, 264
patient and client satisfaction, 256–257
of POCT program, 306–309
of postanalytical processes, 263
of preanalytical processes, 254–256
specimen collection, 255–256
specimen storage, 257
specimen transport, 257
structured, 7
test selection and ordering, 255
total, 7, 8
types and rates of error, **254**
quality management system (QMS), 620
Quality Payment Program (QPP), 74, 620
quality program, 488
Quality System Regulations (QSRs), 33, 580
quantitative theory of management, 6
quantity variance, 440
Quest Diagnostics, 16
"quiet" quitting, 162

R

R_0 ("*R* naught"), 715, 739
race, 382
radiation hazards, 346
radio frequency identification (RFID), 686
radioactive material, 379
RAM (random access memory), 296
random error, 266
ranking system, 172, 189
rapid antigen (Ag) testing, 740

本书版权归John Wiley & Sons Inc.所有

rating systems, 188–189
pros and cons of, **189**
RBEs, *see* results-based evaluations
RCM, *see* revenue cycle management
Reagan, Ronald, 26, 242
reagent availability, 337
real-time PCR, 683, 686, 760
realization rate, 537–538
reason codes, 489
reasonable-charge methodology, 489
reassortment, 715
reassured test criteria, 760
record retention, 501
recovery, 266
redundancy, 296
reengineering, 9
reference-centered testing, 403
reference laboratory, 382
reference laboratory interface, 290
reference range, 266
referral, 69
reflex test, 456, 489
regional integrated laboratory networks, 83–84
regionalization, 83
regulated waste, 362
regulation, 456, 489
regulatory clearance/approval, 336–337
regulatory requirements
CLIA, *see* CLIA '67; CLIA '88
CMS, *see* Centers for Medicare and Medicaid Services
FDA, *see* Food and Drug Administration
for transfusion medicine, 34–36
reimbursement, *see also* billing; fee schedules
administrative policies for, 483–484
basic edits, 479
basic rules for, 478, **479**
beneficiary documents for, 485
charge-based, 68
compliance, *see* compliance
cost-based, 68
date of service rule in, 485
definition of, 68
for diagnosis-related groups, 395
for experimental testing, 483
general criteria for, 478
keys to success in, 472, **472**
local coverage determination for, 482
methods, 68–71
national coverage determinations in, 481–482, **482**
for physician services, 43–44
procedure code edits for, 479
provider documents for, 486
rules and regulations in, 477–489
for screening tests, 482–483, **483**
for special coverage conditions, 484–485
reinforcement learning, 698
relational database, 296
relative risk, 715
relative value units (RVU), 529, 541
reliability, 696
remark codes, 489
remittance advice review
auditing remittance advice, 485
beneficiary documents, 485
provider documents, 485
remote work, 222–223
reporting efficiency, 207
represented by unions, 239
request for proposals (RFP), 292, 296
required rate of return, 440
requisition, 452, 500
design for, 556
research use only, 330
reservoir, 715
resilience, 724
resistance to change, 156
respiratory protection, 352
restructuring, 82
results-based evaluations (RBEs), 188
results interface, 290
résumés, screening, 169–170
retention, 174–175, **175**
retrospective payment system, 456, 472
retrovirus, 715
return on investment (ROI), 541
calculation methods, 547–548
revenue, 17
budget, 429, 440
center, 17
codes, 452
cycle, 19
gross, 17–18
net, 17–18
revenue cycle management (RCM), 537
reviews, in outreach programs, 557
RFID, *see* radio frequency identification
RFP, *see* request for proposals
Richter, Burton, 674
risk, 12
assessment, clinical laboratory workplace safety, 37–38
factor, 715
Robert Wood Johnson Foundation (RWJF), 54
Rogers, "Mister" Fred, 477
ROI, *see* return on investment
ROM (read-only memory), 296
Roosevelt, Theodore, 103
Roper, Stephen, 202
rotation, 415
router, 296
routine shifts, 413–414
Rubino, Louis, 119
Rush, Benjamin, 707
RVU, *see* relative value units
RWJF, *see* Robert Wood Johnson Foundation

S

SaaS, *see* software as a service
Safe Medical Devices Act of 1990, 27
Sagan, Scott T., 717
Saint Ignatius of Loyola, 108
sales personnel, 563–564
sales plan, 521–522
sales report, 569–570
sales team, in outreach programs, 559
SALSA, *see* Saving Access to Laboratory Service Act
SaMD, *see* "software as a medical device"
SAMHSA, *see* Substance Abuse and Mental Health Services Administration
sample, 266
physician letter, 569
sanctioned physicians, 556–557, 568
SARS, *see* severe acute respiratory syndrome
SARS-CoV-1, 715, 740
SARS-CoV-2, 715, 729–730, 740
Saving Access to Laboratory Service Act (SALSA), 456
scalability, 697
scientific management, principles of, 4
screening tests, reimbursement for, 482–483, **483**
SCs, *see* special controls
seasonality, 715
secondary attack rate, 715
secondary container, 362
secondary payor, 456, 462
secondary storage device, 296
Security Amendments Act of 1983, 68
Security Rule, 45
self-actualization, 120
self-appraisal, 189–190
self-designing teams, 214
self-empowerment, 8
self-managed work teams, 214
self-managing teams, 214
self-motivation, 120
semiautonomous work teams, 214
semifixed costs, 529
semivariable costs, 440

本书版权归John Wiley & Sons Inc.所有

sensitivity, 330
analysis, 541
analytical, 266
server, 296
service area, 565–567
service costs, 541
service levels, 383
service location, and coding, 452
severe acute respiratory syndrome (SARS), 709, 715, 740
sewer failure, 380
SGR, *see* sustainable growth rate
Shakespeare, William, 389, 468
shared governance, 11
sharps, 362
regulatory requirements for, 40
"shell lab" provisions, 541
shipping
containers, 368–369
label examples, 370
short-term exposure limit, 362
silo effect, 415
Sinek, Simon, 151
situational analysis, 526
Six Sigma, 9, 311, 620
skill mix, 413, 415, 620
skilled nursing facility (SNF), 462, 484
smallpox, 706–707
smart objectives, 193–194
SNF, *see* skilled nursing facility
SNOMED CT (Systematized Nomenclature of Medicine Clinical Terminology), 330, 452, 672
Snow, John, 707
social and emotional conflicts, 145
social media, 559
Social Security Act of 1967, 478, 489, 494
socio-ecological model of health, 724
software, 286–289
"software as a medical device" (SaMD), 603
software as a service (SaaS), 288, 296
SOPs, *see* standard operating procedures
Sowell, Thomas, 135
special controls (SCs), 33
specialist, 204–205, **205**
specificity, 330
analytical, 266
specimen logistics, 754
specimen type, 335
specimen volume, 335–336
spill management
biological, 355
chemical, 355–356
sponsor responsibilities, 591
staff and staffing, 14, 202–210, 750–751
business need, 203
competence assessment, 204
computation, 691–692
difficulty in finding, 691
education, 203
fixed, 204
flexible, 204, 209
functional definitions, 204
generalist *versus* specialist, 204–205, **205**
increasing patient access, 692
labor shortage, 202–203
medical technologists, increasing opportunities for, 203
personnel requirements, 203–205
productivity measurements, 207
ratio, **205**
reporting efficiency, 207
requirements, 205–206
scheduling, 207–209, **209**
shortages, 53–54
supporting through change, 155–157
training, 204
turnaround time, 207
workload recording, 206
standard, 266, 672
standard cost, 440, 418
standard deviation, 266
standard operating procedures (SOPs), 592
standard precautions, 362
standards of conduct, 489
standing order, 489
Stark Law, *see* Physician Self-Referral Law
STAT testing, 16, 19
state licensing, 452
statistical budget, 429, 440
statute, 456, 489
stay interview, 175, **175**
stem cell research, 648
step-down allocation, 440
step-fixed costs, 440
sterilant, 362
sterilization, 354, **354**, 362
steward, 239
stewardship
definition of, 58
laboratory utilization, 58–60
supply chain instability, 58
stockholder equity accounts, 440
straddling, 404–405
straight-line depreciation, 541
strategic benchmarking, 610
strategic decisions, 10
strategic planning, 12, 396–406, **397**, 519–520, 526
business strategy, *see* business strategy
clinical laboratory industry, structure of, 398–400
competitor analysis, 400–401
failure of, 404–408
formal, **397**
growth trap, 405
hubris, 405
operational efficiency, 396–397
process, 14
profitability trap, 405
straddling, 404–405
strategic positions, in clinical laboratory industry, 401–404, **402**
strategic redesign, 84
strategy, 406
strengths, 400
structured data, 672
structured quality management, 7
study director responsibilities, 591
Substance Abuse and Mental Health Services Administration (SAMHSA), 244, 249
substantially in excess of usual charges, 456, 489
sum of the years digits (SYD) method, 541
summary measure, 620
sunk costs, 541
supervisory staff, weakness of, 412–413
supply chain, 84, 750
definition of, 58
instability, 58
surveillance, 716, 724
surveys, for customer satisfaction, 560
sustainable growth rate (SGR), 74
SWOT analysis, 13, 400, *400*, 526
SYD, *see* sum of the years digits (SYD) method
syndrome, 716
system software, 296
system-wide thinking, development of, 84–85
systematic reviews, 597, 601–603
systems theory, 6–7

T

tactical decisions, 10
target market, 526
task interdependence, 224
TAT, *see* turnaround time
Tax, Equity, Fiscal Responsibility Act of 1982 (TEFRA), 67
Taylor, Frederick, 4
Taylorism, 6, 7
team leader selection, 220
team members
evaluation of, 221
rewarding, 221–222
team(s), 212–224

本书版权归John Wiley & Sons Inc.所有

common purpose, 214–215
costs of, 215–216
definition of, 213, 214
evaluation of, 221
global, 223
goal setting, 220–221
group process and, *216*, 216–217
interdependent tasks, 215, *215*
leading, 219–220
members, selection of, 217–219
performance, 220–221
task-and process-related training, 218–219
types and classifications of, 213–214
virtual, 222–223
technical expertise accessibility, 564
technological advances, 77–80
TEFRA, *see* Tax, Equity, Fiscal Responsibility Act of 1982
TEG, *see* thromboelastography
telecommunication, 80
teleconference, 136, **137**
telemedicine, 81
telepathology, 80
telephone communication, 125
termination, 177–178, **178**
with cause, 177
without cause, 177
terrorism threats, 381–382
test formulary, 632–633
test menu, 336
test script, 296
testing modalities, changing, 78
testing volumes, 336
texting in the workplace, **127**
The Joint Commission (TJC; formerly Joint Commission on Accreditation of Hospitals), 26, 56, 188, 266, 311, 525, 620, 637
competency assessment, 194–197
inspection by, 30
theory X and theory Y, 5
therapeutic studies, 596
thick client architecture, 296
thin client architecture, 296
third party payor, 456
threats, 400
three-day rule (window), 484–485
360-degree evaluations, 190
thromboelastography (TEG), 681, 686
Thucydides, 705
time management, structured approach to, 14
time-of-flight (TOF) mass spectrometry, 686
time value of money, 420–427, 440, 548
tipping point, 724
TJC, *see* The Joint Commission
TLA, *see* total laboratory automation
top-down management, 86
total laboratory automation (TLA), 675, 686
total product life cycle management, 8
total quality management (TQM), 7, 8, 620
Townsend, Robert, 506
Toyota, 7
TQM, *see* total quality management
traditional work teams, 214
traditionalists
behaviors, **112**
communication preferences, **113**
cultural preferences and values, **113**
technology styles, **113**
work style, **113**, **163**
workplace strengths, **112**
workplace struggles, **112**
trainee well-being, 61
transformative, 724
transfusion medicine, 34–36
blood collection, 35
cellular therapies, 36
component production, 35
current and future regulatory challenges, 36
FDA regulations, framework of, 34–35
reporting requirements, 36
services, 35–36
transfusion services, 558
translational research, 597
transmission of infection, 716
transmittal, 489
transportation, 754
Tricare, 456, 462
troublemakers
group, 412
individual, 412
turnaround time (TAT), 83, 207, 263–264, **264**, 266, 283, 330, 336, 686
2-2SD/1-3SD control procedure, *261*

U

UBIT, *see* unrelated business income tax
UCCs, *see* umbilical cord cells
umbilical cord cells (UCCs), 36
unbundling, 457, 489
unclassified device, 48
underperforming employees, 411–412
unfair labor practice (labor organizations), 239
unidirectional interface, 296
union activity management, do's and don'ts of, 241
union membership, 231–232, **232**
union organizing campaign, *235*
authorization cards, 233
bargaining unit, 233
certification, 234
election, 234
information distribution and solicitation, 233–234, **234**
union shop, 239
union steward, function of, 232
union structure
formal, 231
union unfair labor practices, **229**
unionization process, 232–233, **233**
unique provider identifier number (UPIN), 478
unit costs, 529, 541
unit of service (UOS), 417, 418, 420, 427, 441, 620
United States healthcare, 42–44, 55
economy, **44**
Medicare, *see* Medicare
United States Preventive Services Task Force (USPSTF), 483, 489
universal precautions, 362, 716
unrelated business income tax (UBIT), 554, 568
UOS, *see* unit of service
upcoding, 457, 489
UPIN, *see* unique provider identifier number
upstream determinants of health, 724
upward communication, 15, 124
urine drug testing protocol
confirmation, 247
reporting results, 247–248
screening, 247
specimen collection, 244
specimen testing, 244, 247
specimen validity, 248
USB (Universal Serial Bus), 296
USPSTF, *see* United States Preventive Services Task Force
utility failures, 380
utility software, 296
Utrecht Work Engagement Scale, 111

V

vacations, 413–414
vaccines, 735–736
efficacy, 740
hesitancy, 736
VALID, *see* Verifying Accurate Leading-edge IVCT (*in vitro* clinical test) Development Act
validation
of new equipment and procedures, 340–341
plan, 296

本书版权归John Wiley & Sons Inc.所有

value, 489
value-based pay for performance, 466
value-based payment, 472
value-based purchasing (VBP), 74–75
value modifier (VM) program, 75
VAMC, *see* Veterans Affairs Medical Center
VAP, *see* ventilator-associated pneumonia
variable, 716
variable costs, 441, 529, 541
variance, 266
  analysis, 430–434, 441
variant of a virus, 716
variants of concern (VoC), 729, 740
variety-based positioning, 402
VBP, *see* value-based purchasing
vector, 716
vehicle, 716
ventilator-associated pneumonia (VAP), 330
verbal barriers to communication, 128
verification of new equipment and procedures, 340
Verifying Accurate Leading-edge IVCT(*in vitro* clinical test) Development (VALID) Act, 34
vertical consolidation, 54, 55
Veterans Affairs Medical Center (VAMC), 457
veterinary laboratory services, 565
videoconferences, 136–137, **137**
viral pathogens, **713**
Virginia Commonwealth University (VCU), Department of Pathology
  mission statement, 13
  vision statement, 13
virtual slide, 196
virtual teams, 214, 222–223
virtualization, 296
virulence, 716
vision, creation of, 117
vision statements, 13
visual communication, 127
VM, *see* value modifier program
volume variance, 441
von Goethe, Johann Wolfgang, 95
Vroom, V. H, decision-making model, 11
vulnerability, 724

W

Wagner act, *see* National Labor Relations Act (NLRA) of 1935
waived tests, **28**, 311
WAN, *see* wide area network
Warn Act, 177
warning signs and labels, 353
waste management, 356–357
water supply, failure of, 380
WBCs, *see* white blood cells
weaknesses, 400
Weber, Max, 4
website, for outreach program, 559
well-being
  physician, 61
  trainee, 61
Western Electric, productivity studies in, 5
WGS, *see* whole-genome sequencing
white blood cells (WBCS)
  count, 686
  enumeration, 677–678
whole-genome sequencing (WGS), 686, 740
whole-slide imaging (WSI), 80, 196
wide area network (WAN), 287, 297
Wolfe, Nathan, 727
Wooden, John, 226
work group, 224
work-life balance, 118
work practices, 352
work team, 213, 224
worked hours, 620
workflow, 14
worklist, 297
workload recording, 206, 620
workplace drug testing, 242–249
  alternative specimen types, 248, **248**
  analytes and cutoff concentrations, **243**
  clinical and forensic drug testing, management of, 248
  custody and control form, *245*
  for-cause or reasonable suspicion, 244
  instructions, *246*
  nonregulated, 243
  posttreatment testing, 244
  preemployment testing, 244
  random testing, 244
  regulated, 243
  urine drug testing protocol, 244–247
workstation, 297
write-offs, 441
written communication, 125
wrong blood in tube, 698
Wu Lien Teh, 706

X

XML (extensible markup language), 672

Y

yellow fever, 707
Yersin, Alexandre, 706

Z

zero-based budgeting, 441
Ziglar, Z., 67
Zoom fatigue, 224
zoonoses, 704, 716

本书版权归John Wiley & Sons Inc.所有

WILEY END USER LICENSE AGREEMENT

Go to www.wiley.com/go/eula to access Wiley's ebook EULA.

本书版权归John Wiley & Sons Inc.所有